Page 1	Page 2
IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION 	1 APPEARANCES: 2 3 SKIKOS, CRAWFORD, SKIKOS & JOSEPH, LLP BY: MARK G CRAWFORD, ESQUIRE 4 BY: P DYLAN JENSEN, ESQUIRE
IN RE: NATIONAL : MDL NO. 2804 PRESCRIPTION OPIATE LITIGATION : : :	One Sansome Street Suite 2830 San Francisco, California 94104 (415) 546-7300 mcrawford@skikos com djensen@skikos com Representing the Plaintiffs ROBBINS GELLER RUDMAN & DOWD LLP BY: JULIE T HOUGH, ESQUIRE 655 West Broadway San Diego, California 92101 (619) 231-1058 Representing the Plaintiffs BRANSTETTER, STRANCH & JENNINGS, PLLC BY: BENJAMIN A GASTEL, ESQUIRE 223 Rosa L Parks Avenue Suite 200 Nashville, Tennessee 37203 (615) 254-8801 BORGAN, LEWIS & BOCKIUS LLP BY: REBECCA J HILLYER, ESQUIRE 1701 Market Street Philadelphia, Pennsylvania 19103 (215) 963-5000 rebecca hillyer@morganlewis com Representing Teva
Page 3	Page 4
1 APPEARANCES (cont.'d):	1 APPEARANCES VIA TELEPHONE/STREAM (cont.'d):
2 3 JONES DAY BY: SHUBHA M. HARRIS, ESQUIRE	2 3 MARCUS & SHAPIRA LLP BY: DARLENE M. NOWACK, ESQUIRE
4 90 South Seventh Street Minneapolis, Minnesota 55402	4 301 Grant Street, 35th Floor One Oxford Centre
5 (612) 217-8800 shubhaharris@jonesday.com	5 Pittsburgh, Pennsylvania 15219 (412) 471-3490
6 Representing Walmart 7 8 PIETRAGALLO GORDON ALFANO BOSICK &	6 nowack@marcus-shapira.com Representing HBC Services
RASPANTI, LLP 9 BY: DOUGLAS K. ROSENBLUM, ESQUIRE	gibbons p.c.
1818 Market Street 10 Suite 3402	9 BY: PAUL E. ASFENDIS, ESQUIRE One Pennsylvania Plaza
Philadelphia, Pennsylvania 19103 11 (215) 320-6200	10 37th Floor
dkr@pietragallo.com 12 Representing Cardinal Health	New York, New York 10119 11 (212) 613-2000
13 14 APPEARANCES VIA TELEPHONE/STREAM:	pasfendis@gibbonslaw.com 12 Representing AmerisourceBergen Drug Corporation
15 16 ARNOLD & PORTER KAYE SCHOLER LLP	13 14
BY: HEATHER A. HOSMER, ESQUIRE 17 601 Massachusetts Avenue, NW	VIDEOGRAPHER: 15 WILLIAM GEIGERT
Washington, DC 20001 18 (202) 942-5000	16 ALSO PRESENT: JOSEPH WILLS
heather.hosmer@arnoldporter.com 19 Representing Endo Health Solutions Inc.,	17 Precision Trial Services
Endo Pharmaceuticals Inc., Par Pharmaceutical, Inc. and Par Pharmaceutical	18
Companies, Inc.	20 21
22	22
23	23

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Page 5
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                                                                                     Email dated 7/27/2017,
                                                                             Tomsky-5 Bates stamped
  2
                    INDEX
                                                                       2
                                                                                    TEVA MDL A 09019329
  3
                                                                                    through
                                                                                    TEVA_MDL_A_09019333 and
                                                                       3
        Testimony of: SCOTT D. TOMSKY
  5
                                                                                    TEVA_MDL_A_09019546
  6
         By Mr. Crawford
                                      11
                                                                                    through
         By Ms. Hillyer
                                    245, 284
                                                                                    TEVA MDL A 09019551
         By Mr. Gasteel
  7
                                    246
                                                                       5
  8
                                                                             Teva-
                                                                                     Transmittal of
                                                                       6
                                                                             Tomsky-6 Advertisements and
  9
                                                                                    Promotional Labeling for
                                                                                    Drugs and Biologics for
                   EXHIBITS
                                                                                    Human Use, Bates stamped
10
                                                                       8
                                                                                    TEVA MDL A 04342838
                                                                                    through
11
                                                                                    TEVA MDL A 04342849
12
         NO.
                       DESCRIPTION
                                             PAGE
                                                                             Teva- Approval Package for:
Tomsky-7 Application Number:
76-168, 171 pages
                                                                     10
13
                  Scott Tomsky LinkedIn
         Teva-
         Tomsky-1 Profile, 2 pages
14
                                                                                     Code of Federal
                                                                     12
                                                                             Tomsky-8 Regulations Title 21,
                  Teva Opioid Market Share
                                                                                   Section 314 80, 6 pages
         Tomsky-2 Calculation: All Opioids,
15
                                                                     14
                                                                                     Code of Federal
                Bates stamped
                                                                              Tomsky-9 Regulations Title 21,
16
                TEVA MDL A 00455086
                                                                                   Section 314 81, 8 pages
                                                                     15
                through
                                                                     16
                                                                                      Code of Federal
17
                TEVA_MDL_A_00455094
                                                                             Tomsky-10 Regulations Title 21,
18
                  Organization Charts, Bates
                                                                     17
                                                                                   Section 314 98, 4 pages
         Tomsky-3 stamped
                                                                     18
                                                                                     Letter dated December 6,
19
                TEVA_MDL_A_03486562
                                                                             Tomsky-11 2005, 4 pages
                through
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                TEVA_MDL_A_03486593
                                                                                      ANDA Approval and email
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                                                                             Tomsky-12 dated June 03, 2016, Bates
                  Email dated 10/28/2015,
21
         Teva-
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         Tomsky-4 Bates stamped
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                                                                                    TEVA_MDL_A_02922022
                TEVA_MDL_A_04344415, plus
22
                                                                                    through
                attachment, 50 pages
                                                                                    TEVA_MDL_A_02922025
                                                                     22
23
                                                                     23
24
                                                    Page 7
                                                                                                                          Page 8
               Letter dated February 6,
                                                                                      Industry Meeting to
                                                                                                               238
                                                                       1
                                                                              Teva-
       Tomsky-13 2004, 2 pages
                                                                              Tomsky-21 Discuss Opioid Analgesics
 2
                                                                       2
                                                                                     REMS, 7 pages
       Teva- Letter dated June 25,
Tomsky-14 2007, Bates stamped
                                                                       3
                                                                              Teva-
                                                                                       Email chain, top one dated 240
 3
                                                                              Tomsky-22 1/9/2017, Bates stamped
             TEVA_MDL_A_10604467
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 4
             through
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                                                                                     through
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                                                                                     TEVA MDL A 09655244
 5
               Supplement History
                                                                       6
                                                                                       Email chain, top one dated 253
                                                                              Teva-
       Tomsky-15 Oxycodone Hydrochloride
 6
                                                                              Tomsky-23 September 11, 2013, Bates
             Tablets USP, 5 mg, 15 mg
                                                                       7
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             and 30 mg.
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             TEVA MDL A 10602657
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             through
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             TEVA MDL A 10602670
                                                                       9
 9
               Periodic Adverse Drug
                                                                                      Email chain, top one dated 259
10
       Tomsky-16 Experience Report, ANDA:
                                                                     10
                                                                              Tomsky-24 11/1/2013, Bates stamped
             076636.
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             TEVA_MDL_A_11065997
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                                                                                     through
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             through
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             TEVA_MDL_A_11066038
12
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               Letter dated 07/11/2013,
13
                                                                                      Email chain, top one dated 270
       Tomsky-17 Bates stamped
                                                                     13
                                                                              Tomsky-25 1/14/2014, Bates stamped
14
             Acquired_Actavis_00677901
                                                                                     TEVA_MDL_A_10197053 and TEVA_MDL_A_10197054
             through
             Acquired_Actavis_00677905
Letter dated August 17,
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                                                                                      Email dated November 21,
       Tomsky-18 2011, Bates stamped
                                                                              Tomsky-26 2017, Bates stamped
17
             TEVA_MDL_A_10662653
                                                                                     TEVA_MDL_A_11731225
                                                                     16
             through
             TEVA_MDL_A_10662655
                                                                                     through
1.8
                                                                     17
                                                                                     TEVA_MDL_A_11731228
               Letter dated 11/17/2017,
19
       Teva-
                                      235
                                                                     18
       Tomsky-19 Bates stamped
             TEVA_MDL_A_08981645
20
                                                                     19
             through
                                                                     20
             TEVA_MDL_A_08981651
21
                                                                     21
               Letter dated 2014 12 29, 4 236
22
                                                                     22
       Tomsky-20 pages
                                                                     23
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	Page 9		Page 10
1		1	THE VIDEOGRAPHER: Good morning.
2	DEPOSITION SUPPORT INDEX	2	We are now on the record. My name is
3		3	Bill Geigert. I'm a videographer for
4		4	Golkow Litigation Services. Today's date
_	Direction to Witness Not to Answer		-
5	Line	5	is March 5, 2019
6	Line	6	MS. HILLYER: 15.
7		7	THE VIDEOGRAPHER: Yeah, sorry.
8		8	March 15, 2019, and the time is 9:31 a m.
9 10	Request for Production of Documents Page Line	9	This video deposition is being
11	r age Line	10	held in Philadelphia, Pennsylvania, in
12		11	the matter of National Prescription
13		12	Opioid Litigation, for the United States
1.4	Stipulations	13	District Court, Northern District of
14	Line	14	Ohio, Eastern Division. The deponent is
15	Line	15	Scott Tomsky. Counsel will be noted on
16		16	the stenographic record.
17		17	The court reporter is Ann Marie
18	Question Marked	18	Mitchell, and she will now swear in the
19	Question Marked	19	witness.
	Line	20	
20		21	SCOTT D. TOMSKY, after having
21		22	been duly sworn, was examined and
22 23		23	testified as follows:
24		24	
	Page 11		Page 12
		1	5
1		1	
1 2	 EXAMINATION	1 2	answer so we're not talking over each other? A. Yes.
	EXAMINATION		answer so we're not talking over each other? A. Yes.
2		2	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a
2	BY MR. CRAWFORD:	2	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify.
2 3 4		2 3 4	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify.
2 3 4 5	BY MR. CRAWFORD: Q. Good morning. A. Good morning.	2 3 4 5	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a
2 3 4 5 6 7	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I	2 3 4 5 6 7	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me
2 3 4 5 6 7 8	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid	2 3 4 5 6 7 8	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know.
2 3 4 5 6 7 8	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation.	2 3 4 5 6 7 8	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay.
2 3 4 5 6 7 8	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid	2 3 4 5 6 7 8	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know.
2 3 4 5 6 7 8 9	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name?	2 3 4 5 6 7 8 9 10 11	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address?
2 3 4 5 6 7 8 9 10 11	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky.	2 3 4 5 6 7 8 9 10 11	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home
2 3 4 5 6 7 8 9 10 11 12 13	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed	2 3 4 5 6 7 8 9 10 11 12 13	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure.
2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before?	2 3 4 5 6 7 8 9 10 11 12 13 14	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much. It's you're under oath. Correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name of the company?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much. It's you're under oath. Correct? A. Correct.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name of the company? A. I'm not exactly sure or certain
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much. It's you're under oath. Correct? A. Correct. Q. And you know, because we have to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name of the company? A. I'm not exactly sure or certain what the legal name of the company is.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much. It's you're under oath. Correct? A. Correct. Q. And you know, because we have to create a clean record, for me to finish my	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name of the company? A. I'm not exactly sure or certain what the legal name of the company is. Q. And what's your work address?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. CRAWFORD: Q. Good morning. A. Good morning. Q. My name is Mark Crawford, I represent the plaintiffs in the opioid litigation. Can you please state your full name? A. Scott David Tomsky. Q. And have you ever been deposed before? A. Yes. Q. How many times? A. About a dozen. Q. And so you know the rules pretty much. It's you're under oath. Correct? A. Correct. Q. And you know, because we have to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	answer so we're not talking over each other? A. Yes. Q. And if you don't understand a question, please feel free to ask me to clarify. A. Yes. Q. And you're welcome to take a break. If you need to take one, just let me know. A. Okay. Q. Can you please give me your home address? A. Sure. Q. And who is your current employer? A. Teva. Q. What's the full name of your employer? A. Teva USA. Q. Is it is that the legal name of the company? A. I'm not exactly sure or certain what the legal name of the company is.

	Page 13		Page 14
1	Pennsylvania.	1	
2	Q. And did you have any meetings to	2	(A discussion off the record
3	prepare for this deposition today?	3	occurred.)
4	A. Yes.	4	
5	Q. And who did you meet with?	5	BY MR. CRAWFORD:
6	A. Teva counsel, Becca Hillyer.	6	Q. Did you have any other meetings
7	Q. And was anyone else present?	7	with anybody about the deposition?
8	A. There was another attorney. I	8	A. No. There may have been a phone
9	don't remember her name.	9	call, just asking me about my availability and
10	Q. Was that at their offices here in	10	the fact that I'd be asked to be deposed.
11	Philly?	11	Q. And did you review any documents
12	A. Yes.	12	for this deposition?
13	Q. And how long did the meet how	13	A. Yes.
14	many meetings did you have?	14	Q. About how many?
15	A. Just one yesterday.	15	A. I don't know. A couple dozen.
16	Q. And how long?	16	Q. And generally what were they?
17	A. It was from 9:30 in the morning	17	MS. HILLYER: I'll just I
18	until roughly 3:00, 3:30 in the afternoon.	18	don't want him to get into the details of
		19	what they were. He can answer
19 20	Q. And that was yesterday, you said?A. Correct.	20	categorically so that doesn't get into
21		21	the privilege.
22	PHONE SPEAKER: I'm sorry to	22	BY MR. CRAWFORD:
	interrupt.		
23	Would it be possible to move the	23	Q. Go ahead.
24	microphone closer to the witness, please?	24	A. Generally some emails, internal
	Page 15		Page 16
1	reports and documents, presentations.	1	A. He is in charge of global
2	Q. How about, did you review any	2	regulatory affairs.
3	annual reports?	3	Q. And who is his employer?
4	A. What kind of annual reports are	4	A. I'm not sure. I believe it's
5	you asking?	5	Teva UK.
6	Q. To the FDA about your drugs.	6	Q. And is he based in the UK?
7	A. No.	7	A. That's correct.
8	Q. How about approval letters or	8	Q. And why are you reporting to
9	approval packets?	9	somebody in the UK?
10	A. Approval letters.	10	MS. HILLYER: Objection, calls
11	Q. And for which drugs?	11	for speculation.
12	A. The buprenorphine/naloxone,	12	THE WITNESS: I don't know.
	primarily that product.	13	That's my boss when I joined the company,
13	printarny that product.		
	Q. And how general in your	14	and it's who I've been reporting to since
13		14 15	and it's who I've been reporting to since I joined.
13 14	Q. And how general in your		1 0
13 14 15	Q. And how general in your department, what's your current position at Teva?	15	I joined.
13 14 15 16	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North	15 16	I joined. BY MR. CRAWFORD:
13 14 15 16 17	 Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. 	15 16 17	I joined. BY MR. CRAWFORD: Q. And he's he works for a
13 14 15 16 17 18	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. Q. And what's the name of your	15 16 17 18	I joined. BY MR. CRAWFORD: Q. And he's he works for a different company than your company, though.
13 14 15 16 17 18 19	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. Q. And what's the name of your department at Teva?	15 16 17 18 19	I joined. BY MR. CRAWFORD: Q. And he's he works for a different company than your company, though. MS. HILLYER: Objection to form.
13 14 15 16 17 18 19 20	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. Q. And what's the name of your department at Teva? A. Regulatory affairs.	15 16 17 18 19 20	I joined. BY MR. CRAWFORD: Q. And he's he works for a different company than your company, though. MS. HILLYER: Objection to form. BY MR. CRAWFORD:
13 14 15 16 17 18 19 20 21	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. Q. And what's the name of your department at Teva? A. Regulatory affairs. Q. And who is your immediate	15 16 17 18 19 20 21	I joined. BY MR. CRAWFORD: Q. And he's he works for a different company than your company, though. MS. HILLYER: Objection to form. BY MR. CRAWFORD: Q. Is that correct?
13 14 15 16 17 18 19 20 21 22	Q. And how general in your department, what's your current position at Teva? A. So I'm vice president of North American generic regulatory affairs. Q. And what's the name of your department at Teva? A. Regulatory affairs. Q. And who is your immediate superior?	15 16 17 18 19 20 21 22	I joined. BY MR. CRAWFORD: Q. And he's he works for a different company than your company, though. MS. HILLYER: Objection to form. BY MR. CRAWFORD: Q. Is that correct? A. I believe so.

1	Page 17		Page 18
	the company he works for?	1	as far as maybe the past month, what have your
2	A. I'm not certain.	2	meetings been about with Ms. Fridriksdottir?
3	Q. And who does Mr. Banks report to	3	A. Status of applications.
4	right now?	4	Q. And do you have any
5	A. He reports to the global head of	5	responsibility first of all, let's go back.
6	research and development.	6	Let's mark the first exhibit,
7	Q. And who is that?	7	which will be a LinkedIn profile.
8	A. Her name is Hafrun. And her last	8	
9	name is Fridriksdottir.	9	(Deposition Exhibit No.
10	Q. And where is Ms. Fridriksdottir	10	Teva-Tomsky-1, Scott Tomsky LinkedIn
11	located?	11	Profile, 2 pages, was marked for
12	A. In Parsippany, New Jersey.	12	identification.)
13	Q. And who is her employer?	13	
14	A. I'm not certain.	14	BY MR. CRAWFORD:
15	Q. And do you have any opportunity	15	Q. We're going to flash the
16	to interact with Ms. Fridriksdottir?	16	documents on the screen up here, and also I'll
17	A. Yes.	17	provide you with a copy.
18	Q. On a pretty regular basis, I mean	18	A. Okay.
19	like at least once a week?	19	MS. HILLYER: This is LinkedIn?
20	MS. HILLYER: Objection to form.	20	MR. CRAWFORD: Yeah.
21	THE WITNESS: Yes. Regularly,	21	MS. HILLYER: Doesn't look like
22	once a week.	22	it.
23	BY MR. CRAWFORD:	23	MR. CRAWFORD: I actually figured
24	Q. And generally what comes to mind	24	out how to print a LinkedIn profile so it
	Page 19		Page 20
1	doesn't look like it's from a web page.	1	A. Yes.
2	So you have to go to the little three	2	Q. And what is the base salary right
3	dots next to the name, and that gives you	3	now?
4	an option.	4	A. Roughly \$315,000.
5	MS. HILLYER: Good to know.	5	Q. And do you also get stock options
6	MR. CRAWFORD: Much cleaner.	6	
_		0	or bonuses, stock as bonuses?
7	BY MR. CRAWFORD:	7	or bonuses, stock as bonuses? A. Occasionally, yes.
7	BY MR. CRAWFORD: Q. Does this look like generally		
		7	A. Occasionally, yes.
8	Q. Does this look like generally	7 8	A. Occasionally, yes.Q. And is there a cash type of bonus that you can get achieve?A. Yes.
8 9 10 11	Q. Does this look like generally what's on your LinkedIn page?	7 8 9 10 11	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or
8 9 10 11 12	 Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. 	7 8 9 10 11 12	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with
8 9 10 11 12 13	 Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your 	7 8 9 10 11 12 13	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses?
8 9 10 11 12 13 14	 Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, 	7 8 9 10 11 12 13 14	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual
8 9 10 11 12 13 14 15	 Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, 	7 8 9 10 11 12 13 14 15	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and
8 9 10 11 12 13 14 15	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America?	7 8 9 10 11 12 13 14 15	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company
8 9 10 11 12 13 14 15 16	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct.	7 8 9 10 11 12 13 14 15	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance.
8 9 10 11 12 13 14 15 16 17	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this	7 8 9 10 11 12 13 14 15 16 17	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the
8 9 10 11 12 13 14 15 16 17 18	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look	7 8 9 10 11 12 13 14 15 16 17 18	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count
8 9 10 11 12 13 14 15 16 17 18 19 20	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look accurate to you?	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus?
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look accurate to you? A. Yes.	7 8 9 10 11 12 13 14 15 16 17 18	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus? A. Generally, new submissions that
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look accurate to you? A. Yes. Q. Let me ask you briefly about your	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus? A. Generally, new submissions that are being made to the FDA. The number of
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look accurate to you? A. Yes. Q. Let me ask you briefly about your compensation, current compensation.	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus? A. Generally, new submissions that are being made to the FDA. The number of first-to-file submissions that are made to FDA
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Does this look like generally what's on your LinkedIn page? A. Generally, yes. Q. And did you prepare this? A. Yes. Q. All right. And this is your current position here, July 2013 to the present, Teva Pharmaceuticals, VP regulatory affairs, generics, North America? A. Correct. Q. And is the rest of this information, just scanning it, does that look accurate to you? A. Yes. Q. Let me ask you briefly about your	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Occasionally, yes. Q. And is there a cash type of bonus that you can get achieve? A. Yes. Q. And what is the basis for or criteria the company uses to provide you with stock or cash bonuses? A. It's based on individual performance, regulatory affairs group goals and key performance indices, as well as company performance. Q. And generally what are the regulatory affairs goals that achieve or count towards a bonus? A. Generally, new submissions that are being made to the FDA. The number of

	Page 21		Page 22
1	year. Approvals. Maintaining compliance with	1	of \$100,000 of stock.
2	FDA regulations with respect to filing of annual	2	Q. And that would be of Teva Limited
3	reports. And as well as, you know, development	3	stock?
4	of staff.	4	A. It is of Teva stock in the US,
5	Q. And who conducts a review for you	5	whatever stock is on the stock exchange in the
6	for this bonus?	6	US.
7	A. My boss in the UK, Michael Banks.	7	Q. That would be Teva Pharmaceutical
8	Q. And is there generally a	8	Industries Limited?
9	performance review that you receive, a written	9	A. I'm not certain of the legal
10	one?	10	entity.
11	A. Yes.	11	Q. Do you know who your parent
12	Q. And just last year, what was your	12	company is, of your employer?
13	bonus that you received, the last bonus you	13	A. I mean, I don't get into the
14	received?	14	legal entities. There's so many type of legal
15		15	entities, so I'm honestly not certain.
16	A. Roughly the I guess the payout before taxes was roughly \$137,000.	16	•
17	Q. And any stock?	17	Q. Do you interface with any regulatory personnel in Israel for the company?
18	A. Yes.	18	
19	Q. And how much was that?	19	·
20	A. I honestly don't remember.	20	Q. And who is that?A. It would be Osnat is her first
21	Roughly I don't I'm not certain.	21	
22	Q. Can you take a rough guess,	22	name.
23	please?	23	Q. How do you spell that?A. O-S-N-A-T. Cohen is her last
24	A. I believe somewhere in the range	24	name, C-O-H-E-N.
24	A. I believe somewhere in the range	24	name, C-O-11-L-IV.
	Page 23		Dago 24
	1490 25		Page 24
1	Q. And what's her position?	1	mean, I'll list everybody's name who I
1 2		1 2	
	Q. And what's her position?		mean, I'll list everybody's name who I
2	Q. And what's her position?A. I believe she's a director in	2	mean, I'll list everybody's name who I worked in Israel with?
2	Q. And what's her position?A. I believe she's a director in regulatory affairs.	2 3	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD:
2 3 4	Q. And what's her position?A. I believe she's a director in regulatory affairs.Q. Is it for Israel or global or	2 3 4	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've
2 3 4 5	 Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory 	2 3 4 5	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with.
2 3 4 5 6	 Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions 	2 3 4 5 6	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in
2 3 4 5 6 7	 Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And 	2 3 4 5 6 7	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel.
2 3 4 5 6 7 8	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would	2 3 4 5 6 7 8	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance.
2 3 4 5 6 7 8	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the	2 3 4 5 6 7 8	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013.
2 3 4 5 6 7 8 9	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings.	2 3 4 5 6 7 8 9	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah.
2 3 4 5 6 7 8 9 10	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a	2 3 4 5 6 7 8 9 10	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD:
2 3 4 5 6 7 8 9 10 11	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want	2 3 4 5 6 7 8 9 10 11	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who
2 3 4 5 6 7 8 9 10 11 12 13	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US?	2 3 4 5 6 7 8 9 10 11 12 13	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember.
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US? A. So any product that is being	2 3 4 5 6 7 8 9 10 11 12 13 14	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember. MS. HILLYER: In regulatory? Do
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US? A. So any product that is being manufactured in Israel, if that product was going	2 3 4 5 6 7 8 9 10 11 12 13 14 15	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember. MS. HILLYER: In regulatory? Do you want to narrow it at all?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US? A. So any product that is being manufactured in Israel, if that product was going to be submitted to the FDA, her team would manage	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember. MS. HILLYER: In regulatory? Do you want to narrow it at all? MR. CRAWFORD: Let's start with
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US? A. So any product that is being manufactured in Israel, if that product was going to be submitted to the FDA, her team would manage the documents and send them to my team here in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember. MS. HILLYER: In regulatory? Do you want to narrow it at all? MR. CRAWFORD: Let's start with regulatory, yeah.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And what's her position? A. I believe she's a director in regulatory affairs. Q. Is it for Israel or global or A. So she manages the regulatory team that is in Israel. So any submissions coming out of Israel her team would work on. And if it's a submission coming to the US, they would coordinate documents for the US team for the filings. Q. So what do you mean by a submission from Israel? A drug that they want approved in the US? A. So any product that is being manufactured in Israel, if that product was going to be submitted to the FDA, her team would manage the documents and send them to my team here in the US.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	mean, I'll list everybody's name who I worked in Israel with? BY MR. CRAWFORD: Q. Yes, please. That you've interfaced with. A. Everybody that I spoke to in Israel. Q. Right. Of any substance. MS. HILLYER: Since 2013. MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. Maybe moving backwards, just who you can remember. MS. HILLYER: In regulatory? Do you want to narrow it at all? MR. CRAWFORD: Let's start with regulatory, yeah. THE WITNESS: So Sigal Molgan is
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Page 25 Page 26 1 She is just a part of the 1 names, but there would have been several members 2 2 regulatory affairs team in Israel. of the regulatory affairs team there that would 3 have supported submissions in some way. 3 And what were the discussions 4 about that you recall? 4 Q. How about other departments in --5 A. Nothing of substance. It was 5 I don't mean just small chitchat, anyone that 6 about products. So I can't specifically recall 6 you've had, you know, kind of, you know, more 7 what product we spoke about, but... 7 than a passing conversation, that you interfaced 8 8 Anyone else? with in Israel? O. 9 9 A. Sure. Who else? Daniella MS. HILLYER: Objection to form. 10 THE WITNESS: Yeah. I mean, I 10 Gutman. And what's her position? 11 can't -- any conversations with anybody 11 O. She is in charge of research and 12 in Israel would have been related to 12 13 development in Israel. 13 product filings that were being prepared 14 14 And Gutman, how do you spell for the US. Q. 15 15 BY MR. CRAWFORD: that? 16 16 G-U-T-M-A-N, I believe. Q. That helps. Thank you. A. 17 Do you recall the substance of 17 Okay. Prior to -- let me ask you 18 those conversations? 18 this: So at Teva, do you have any responsibility 19 Again, they would have been 19 for opioid products currently? 20 A. Can you clarify what you mean by 20 product related, about a product that they were 21 working on for submission to the US. 21 responsibility? 22 22 Q. Well, let's go back to this Q. Anyone else come to mind in 23 regulatory? 23 question. 24 24 What -- can you generally A. I'm having a hard time recalling Page 27 Page 28 describe your duties at Teva? 1 1 those products. From a high level, that's what 2 A. Sure. So the regulatory affairs 2 the regulatory affairs team does. 3 team is the main liaison between FDA and the 3 Q. So basically, as far as 4 company. So the regulatory affairs teams 4 interfacing directly with the FDA on issues, it's 5 coordinate ANDA, my team in the generic space 5 primarily run through your department. Right? 6 coordinates ANDA submissions to the FDA. So it 6 MS. HILLYER: Objection to form. 7 7 collects documents from the manufacturing sites THE WITNESS: So the regulatory 8 where a product is to be manufactured. It puts 8 affairs team manages the approval process 9 that information together into the ANDA format 9 for new ANDAs and then maintaining 10 that FDA expects. It makes the submissions to 10 compliance in terms of submissions of 11 the FDA and works with FDA. If FDA has any 11 annual reports and keeping those 12 follow-up questions, the regulatory affairs team 12 submissions up to date. 13 would receive that information from the FDA, it 13 BY MR. CRAWFORD: 14 would coordinate a call with internal 14 Q. How about communications with the 15 stakeholders who are responsible for that product 15 FDA? If the FDA wants to talk about a drug or 16 16 and coordinate a response back to FDA. some issue, is it your department that generally 17 So it's getting products 17 interfaces directly with them, or -approved. It's maintaining compliance of 18 18 A. It would depend. 19 approved products in terms of filing annual 19 Q. Okay. 20 reports each year. If there are any changes to 20 A. It would depend. If it was 21 an application, any document that's been 21 related to an application we filed and a specific 22 22 previously submitted to FDA, the regulatory question about that application, it would be us. 23 affairs team will coordinate the updates and make 23 But it could also be the quality team. If it was 24 possibly supplemental submissions to the FDA for 24 related to a product complaint, it would go

	Page 29		Page 30
1	through the quality group. If it was related to	1	A. There is a group located in
2	an adverse event, it would go through the	2	Horsham, Pennsylvania. There is a group located
3	pharmacovigilance group.	3	in Parsippany. And then there's also some
4	Q. But any written submission to the	4	individuals in India as well.
5	FDA generally runs through your department as far	5	Q. And then pharmacovigilance let
6	as maybe final looking at it or approval or	6	me go back.
7	signing it?	7	So regulatory operations, that's
8	A. Not necessarily	8	currently.
9	MS. HILLYER: Objection to form.	9	How about in the beginning when
10	THE WITNESS: Sorry.	10	you arrived, where was regulatory operations run
11	MS. HILLYER: That's okay.	11	out of?
12	THE WITNESS: Not necessarily.	12	A. So I would say when I began at
13	So, for example, for pharmacovigilance	13	Teva in July of 2013, the regulatory so
14	activities, the pharmacovigilance team	14	regulatory operations was transitioning away from
15	would prepare all reports. And then	15	the regulatory group and starting a shared
16	before it goes to FDA, there is a	16	services group, how they are set up now.
17	regulatory operations group, which is not	17	Q. And did that occur with the
18	under my responsibility. And they simply	18	Actavis acquisition or prior?
19	take the content from the	19	A. No. That was prior to the
20	pharmacovigilance team and submit it to	20	Actavis.
21	FDA via the FDA electronic gateway.	21	Q. And then pharmacovigilance, where
22	BY MR. CRAWFORD:	22	are those reports kind of managed or collected
23	Q. Where is the regulatory	23	up?
24	operations group located?	24	MS. HILLYER: Objection to form.
	Page 31		Page 32
			raye 32
1	<u> </u>	1	
1 2	THE WITNESS: Yeah, I'm not sure.	1 2	But who else is involved from
2	THE WITNESS: Yeah, I'm not sure. Can you clarify your question?	2	But who else is involved from pharmacovigilance outside of those two sites,
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	Page 33		Page 34
1	prepares applications for generic drugs that are	1	and consistent from one part of the
2	called ANDAs, abbreviated new drug applications.	2	application to the next.
3	Correct?	3	And then certain sections of the
4	A. Yes.	4	ANDA my team would draft.
5	Q. And they're in writing,	5	BY MR. CRAWFORD:
6	presumably, and submitted to the FDA. Correct?	6	Q. And then for once a drug is
7	A. Correct. Electronically.	7	approved, a generic drug, the company is required
8	Q. And there are written portions of	8	at certain points to submit the annual reports.
9	it.	9	Right?
10	And I'm trying to find out if	10	A. Yes.
11	your department is involved in preparing the	11	Q. And who prepares those annual
12	written portions of the ANDA?	12	reports? What's the process for putting one
13	A. Yes.	13	together?
14	Q. Does your department draft it or	14	A. Current process?
15	review it or is it a multi-department function?	15	Q. Yeah.
16	MS. HILLYER: Objection to form.	16	A. So current process is much of
17	THE WITNESS: Yeah, it's a	17	this activity has been moved overseas to India.
18	combination. So my team works with the	18	Q. And is it what company does it
19	R&D team, the research and development	19	in India?
20	team that's working on that product.	20	A. I'm not certain of the legal
21	Certain sections will come in drafted	21	entity name.
22	from the R&D department. My team will	22	Q. Is it a Teva-related company or
23	edit those documents to make sure that	23	is it a third-party company?
24	the documents flow and are easy to read	24	A. It's Teva.
	Page 35		D 26
	1490 33		Page 36
1	Q. So that department or in	1	in India or
1 2	Q. So that department or in India, they're putting together the annual	1 2	in India or A. Yes.
	Q. So that department or in India, they're putting together the annual reports from various departments that are needed		in India or A. Yes. Q. Okay. So who's the person in
2	Q. So that department or in India, they're putting together the annual	2	in India or A. Yes. Q. Okay. So who's the person in India that's responsible for that?
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Page 37 Page 38 1 directly if there are no questions. 1 And that's generally the name 2 2 Q. And the generic drug labels, the brand drug. Right? 3 3 Yes. package insert, is it your understanding that A. 4 they generally have to be the same or 4 But if it's withdrawn, it can be 5 substantively the same as the name-brand labels? 5 another generic that the FDA designates. Right? 6 Yes. 6 That's correct. A. 7 And if there's a change to the 7 Go ahead. 8 name-brand label, is it your understanding that 8 So they'll monitor the FDA 9 your company needs to change the generic label to 9 website for any products that we have approved 10 substantively match the name-brand drug label? and even pending which are under review at FDA, 10 11 11 to ensure that the labeling is kept up to date. A. Yes. 12 12 And they'll make the changes and revisions to our And is there a process right now 13 to monitor those changes and to update the 13 label. And then they would make a -- if it's an generic labels for submission to the FDA? 14 approved product, they would make a CBE 14 15 A. Yes. 15 supplement submission to the FDA. And if it's a 16 And can you explain that process 16 pending product, they would prepare the label and Q. 17 now? 17 work with the regulatory associate who's 18 18 responsible for that product to coordinate the Yes. So the labeling team is a 19 part of my responsibility. They're currently 19 submission to the FDA for that pending product. 20 based in North Wales, Pennsylvania and 20 Q. Right. And by CBE, you mean 21 Parsippany, New Jersey. But they monitor the 21 changes being effected, meaning that you could do 22 FDA's website for any RLD updates to labels. 22 it automatically without FDA preapproval. Right? 23 RLD being reference listed drug? 23 That's correct. 2.4 A. Yes. 2.4 Generally is there a target Page 39 Page 40 turnaround time between the RLD change and when 1 1 A. I believe so. I'm not certain if 2 you would like to have the Teva change to the 2 it's a standard operating procedure or a work 3 generic label to the FDA? 3 instruction. 4 A. It varies. So it's really 4 Q. But it is in writing? 5 dependent on the types of changes that are made 5 Yes. A. 6 for the RLD product. If it's safety or labeling 6 Q. Have you seen that before? 7 changes, we try to do those more quickly in 7 A. Yes. 8 accordance with a procedure. But if it's 8 This process for updating the 9 administrative changes, then, you know, those 9 label when the RLD does, has that always been 10 would take a little bit longer and less priority. 10 that way since you got there? And if not, what 11 Q. If it's safety, what -- is there 11 was it before? 12 a target time that you have for that? 12 A. I'm sorry, can you repeat your A. To turn it around within 30 days. 13 13 question? 14 Q. And is there a standard operating 14 15 procedure or guideline, written one, the company 15 So there's a process for updating 16 has on that process? your label if there's a change by the brand or 16 17 A. I believe so, yes. 17 the RLD. And you just described it. 18 Q. Is there a standard operating 18 Has that process changed over the 19 procedure written guideline for preparing annual 19 time since you've been there, and if so, how has 20 reports on those generic drugs? 20 21 A. There would be a work 21 A. It may have. I'm not certain. 22 instruction, I believe. 22 When I first joined the company, labeling wasn't 23 Q. Is that what it's officially 23 part of my team's responsibility. And it became 24 called in the company, a work instruction? 24 part of my team's responsibility with the Actavis

	Page 41		Page 42
1	acquisition. So I'm not certain if it's changed	1	patients and dispensed by legal pharmacists.
2	since that time or not.	2	Q. And the REMS process was a
3	Q. So that responsibility landed	3	process that was codified back in 2007 by
4	with your department in about 2016 or '17?	4	Congress. Right?
5	A. Roughly, yes.	5	A. That's correct.
6	Q. Because Actavis was acquired	6	Q. And it gave the FDA authority to
7	the generic Actavis company was acquired in 2016	7	require a plan of some sort for for supporting
8	by Teva. Right?	8	the safety of the drugs on the market. Right?
9	A. That's correct.	9	A. To ensure that the benefits of
10	Q. And you're not sure what the	10	the drug still outweigh the risks. And that the
11	process was before it arrived at your department?	11	drugs that have been approved by FDA are still,
12	A. No, I'm not certain.	12	you know, prescribed and used as directed and as
13	Q. What about you're familiar	13	according to the approved labeling by the FDA.
14	with the term "REMS." Right?	14	
	_		Q. And currently there are REMS in
15		15	place for opioid products, at least some opioid
16	Q. What does that stand for?	16	products manufactured and distributed by Teva.
17	A. Risk evaluation and mitigation	17	Right?
18	strategies.	18	A. There's REMS in place for several
19	Q. Can you briefly describe what a	19	different kinds of products, but opioids being
20	REMS is?	20	one, yes.
21	A. Sure. So REMS are put in place	21	Q. Is part of the REMS process is
22	to ensure that the benefits of the drug still	22	for those opioids, if you know, deal with kind of
23	outweigh the risk when used when they're	23	educating doctors about the proper use and risks
24	prescribed by doctors, when they're used by	24	associated with those opioid products?
	Page 43		Page 44
1		1	
1	A. I'm not certain of the specifics	1	past several years. The coordination efforts between FDA and many of the manufacturers who are
2	of the opioid REMS. I mean, I haven't been closely involved in that process.	3	involved in these REMS has really impacted
3	*		·
4	Q. Have you reviewed them before?	4	approval times. So in order to better align and
5	A. I have not reviewed it.	5	ensure communications within the regulatory team
6	Q. What department is responsible	6	and the REMS team, it was moved to regulatory
7	for making sure Teva's obligations under those	7	affairs.
8	plans are	8	Q. And that's your department.
9	A. So there's a REMS	9	Right?
10	Q. Go ahead.	10	A. That's correct.
11	A. Sorry. So there is a REMS group.	11	Q. And explain to me how it was a
			· · · · · · · · · · · · · · · · · · ·
12	It's actually it was actually a part of the	12	roadblock to regulatory approval, the REMS.
12 13	It's actually it was actually a part of the commercial organization until October of 2018, of	13	roadblock to regulatory approval, the REMS. A. Generally speaking
12 13 14	It's actually it was actually a part of the commercial organization until October of 2018, of which time it moved to my responsibility.	13 14	roadblock to regulatory approval, the REMS. A. Generally speaking MS. HILLYER: I'm sorry.
12 13 14 15	It's actually it was actually a part of the commercial organization until October of 2018, of which time it moved to my responsibility. Q. So "commercial," you mean the	13 14 15	roadblock to regulatory approval, the REMS. A. Generally speaking MS. HILLYER: I'm sorry. Objection to form.
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Page 45 Page 46 1 FDA assigns to an application. So if 1 FDA gives to you and says, follow this directly. 2 2 it's taking the REMS process an extremely It's something that you prepare 3 3 to submit that the FDA will approve and is long time, if a goal date when FDA plans 4 to take an action on an application comes 4 acceptable to them. Right? 5 5 MS. HILLYER: Objection to form. up, the FDA will issue a deficiency 6 6 THE WITNESS: So it's something letter because the REMS is not yet 7 7 that a generic applicant would have to approved. 8 BY MR. CRAWFORD: 8 work with the reference listed drug 9 9 So it was the interfacing with holder and any other manufacturers. BY MR. CRAWFORD: 10 10 the other manufacturers to get an acceptable REMS 11 Q. And so the delay was really when 11 that you could submit to the FDA that was holding 12 you submitted -- there is a deadline, right, from 12 things up? 13 the time that the application for the generic 13 A. That's part of it. It's also drug is submitted that the FDA is to take some 14 14 coordination from FDA and within FDA of the REMS 15 kind of action, either approving it or not 15 group at FDA and then the reviewing groups in the 16 approving it. Right? 16 Office of Generic Drugs. 17 A. That's correct. 17 Q. So when you get approval of a 18 If one of the conditions of 18 generic drug that has to have a REMS, a risk 19 approval was having an acceptable REMS, and you 19 evaluation and mitigation strategy, you have to 20 didn't submit that, they would -- they would --20 submit with your approval package a version of it 21 that deadline would come and they would just that -- if it's a class-wide REMS, that's -- that 21 22 simply not approve it and say it was deficient 22 is consistent with the class-wide REMS. Right? 23 because it didn't have a REMS. 23 That's correct. 24 Is that the concern? 24 But it's not something that the Q. Page 47 Page 48 1 1 other manufacturers to have agreements in Not necessarily that it wasn't 2 2 submitted. It could be that it was submitted but place establishing the single shared 3 3 REMS. So it's working with not only the FDA still hasn't had an opportunity to complete 4 its review of it, or FDA may have further changes 4 companies, it's working with vendors to 5 that it would like to it. So it could be a 5 ensure that all the elements of the REMS are in place. 6 number of variables. 6 7 Q. Got it. Okay. Thank you. 7 BY MR. CRAWFORD: 8 So before the function was moved 8 Q. Okay. But the company either --9 to regulatory in October 2018 and it was in the 9 I mean, somehow the company has obligations, but 10 hands of the commercial department or marketing 10 they're coordinating with other companies to 11 department, what was the process for assuring 11 fulfill them. Right? 12 adherence to the REMS, do you know? 12 A. That's correct. MS. HILLYER: Objection to form. 13 13 And I'm just asking what was the THE WITNESS: I'm not clear of 14 14 process prior to coming to you within the 15 15 commercial or marketing department to make sure your question. 16 BY MR. CRAWFORD: 16 Teva's obligations in coordination with the other 17 Q. Okay. So what did that -- part 17 manufacturers were being complied with? MS. HILLYER: Objection to form. 18 of the department's function currently with 18 19 regard to the REMS is to make sure that the 19 THE WITNESS: So again, prior to 20 company's compliant with the REMS provisions. 20 it coming to my organization, I'm not 21 Right? 21 entirely clear what the processes were. MS. HILLYER: Objection to form. 22 22 My team would just work with the REMS 23 THE WITNESS: So no. The REMS 23 associate that was responsible for a 24 team's responsibility is to work with the 24 product to make sure that we had the

	Page 49		Page 50
1	proper documents in our application.	1	Q. All right. And Kishore is
2	BY MR. CRAWFORD:	2	K-I-S-H-O-R-E?
3	Q. So who was in charge with the	3	A. That's correct.
4	commercial or marketing department over the REMS	4	Q. So he's head of the REMS team for
5	programs prior to coming to your department? Is	5	the opioid REMS?
6	there a person or individual who kind of was in	6	A. He's head of the REMS team for
7	charge?	7	all REMS.
8	A. So you're asking who the REMS	8	Q. And how long has he been in that
9	team reported to, which person?	9	position, do you know?
10	Q. Who was head of the REMS team	10	A. I'm not certain how many years.
11	back then?	11	Q. At least since you've been there?
12	A. It's the same person who's head	12	A. Yes.
13	of the REMS team now, his name is Kishore	13	Q. And who does he report to now?
14	Durgen sorry, Kishore Gopu.	14	A. He reports to me.
15	Q. How do you spell that?	15	Q. And who did he report to prior to
16	A. G-O-P-U is his last name.	16	you?
17	Q. Is he based in Mumbai?	17	A. Tim McFadden.
18	A. No.	18	Q. And where is Mr. McFadden
19	Q. Where is he?	19	located?
20	A. He's in Parsippany.	20	A. Parsippany.
21	Q. Does he work do you know who	21	Q. And what is his position?
22	he works for?	22	A. I'm not sure what his title is.
23	A. He works for Teva. I'm not sure	23	Q. But he's with the commercial or
24	of the legal entity name.	24	marketing department?
	or the regar chirty mane:		
	Page 51		Page 52
1	A. Yes.	1	the data from these third-party vendors who
2	Q. And so now you're really	2	manage the REMS components and we would and
3	responsible at least ultimately for the REMS	3	actually, they put together even the reports and
4	compliance. Right?	4	send it to each of the companies participating in
5	MS. HILLYER: Objection to form.	5	that REMS. And then my team would put a cover
6	THE WITNESS: So not for REMS	6	letter on it and make that submission to the FDA.
7	compliance. I'm responsible for ensuring	7	Q. And what are these companies?
8	that the components of the REMS and	8	What
9	what's required to be submitted to the	9	MS. HILLYER: Objection to form.
10	FDA has been submitted to the FDA. But	10	BY MR. CRAWFORD:
11	maintaining compliance, again, these REMS	11	Q. Can you identify them?
12	programs are quite complicated, they're	12	A. I'm sorry, can you repeat your
13	managed by third parties outside of Teva.	13	question?
14	So they're the ones who would track and	14	Q. What are the third-party vendors
15	do any of the, you know, compliance	15	who are doing this REMS function for you?
	checks. But we would coordinate the data	16	A. I mean, I believe UBC is one.
16		1	McKesson is another.
16 17	from those companies and then submit	17	IVICKESSOII IS AHOUREI.
	from those companies and then submit regular reports to FDA about that	17	Q. McKesson?
17	_		
17 18	regular reports to FDA about that	18	Q. McKesson?
17 18 19	regular reports to FDA about that compliance.	18 19	Q. McKesson? A. Yes.
17 18 19 20	regular reports to FDA about that compliance. BY MR. CRAWFORD:	18 19 20	Q. McKesson?A. Yes.Q. Okay.
17 18 19 20 21	regular reports to FDA about that compliance. BY MR. CRAWFORD: Q. So your department is responsible	18 19 20 21	Q. McKesson?A. Yes.Q. Okay.A. But I'm not certain of any of the
17 18 19 20 21 22	regular reports to FDA about that compliance. BY MR. CRAWFORD: Q. So your department is responsible for the regular any regular reporting	18 19 20 21 22	Q. McKesson?A. Yes.Q. Okay.A. But I'm not certain of any of the other names.

	Page 53		Page 54
1	that comes through your department ultimately	1	A. It was in Philadelphia.
2	then and now?	2	Q. At Golkow or where?
3	A. So again, it wouldn't come from	3	A. No. Traurig. I don't remember
4	my department.	4	the firm name, actually.
5	Q. Through.	5	Q. Was it the questioning attorney's
6	A. My department right. My	6	firm?
7	department would receive the reports from these	7	A. I believe no, I believe it was
8	vendors and make the submissions to the FDA.	8	a Teva firm.
9	Q. Have you ever been deposed in an	9	Q. Do you remember the name of the
10	opioid-related case?	10	lawyer who took the deposition?
11	A. I mean, I've been deposed on	11	A. No, I do not.
12	products that were of the subclass of opioids.	12	Q. Any other opioid cases or
13	Q. And can you generally tell me	13	opioid-related cases that you were deposed in?
14	what those cases were? I mean, who was the	14	A. None that come to mind.
15	plaintiff and, you know, what were they about?	15	Q. Going back to Exhibit 1, which is
16	A. I mean, the plaintiff was a	16	your LinkedIn page, you write in the summary,
17	patient who allegedly took an opioid product and	17	"aggressively identifying opportunities," "proven
18	had an event.	18	record."
19	Q. And where was that case based out	19	What is that? What opportunities
20	of? Do you know what court or state?	20	are you referring to?
21	A. I'm not certain.	21	A. I think it's talking about
22	Q. And when was that deposition?	22	regulatory strategy.
23	A. Last week, actually.	23	Q. What kind of strategies?
24	Q. And where was that deposition?	24	A. When to make a submission, what
	Page 55		Page 56
1	should be included in the application, things	1	responsibilities in that position?
2	like that.	2	A. Similar to my current
3	Q. Okay. And then it says, "proven	3	responsibilities now. Again, it was overseeing
4	record ofdriving profitable growth."	4	the regulatory US generics regulatory affairs
5	What do you do that drives	5	team and the Canadian regulatory affairs team for
6	profitable growth?	6	submissions to the FDA and as well as maintaining
7	A. It's just trying to find		
· '	J J J J J	7	compliance in terms of filing annual reports and
8	efficiencies in the work that we're doing. It's	7 8	compliance in terms of filing annual reports and post-approval change supplements to the FDA.
8	efficiencies in the work that we're doing. It's	8	post-approval change supplements to the FDA. Q. And does Ranbaxy manufacture, sell or distribute any opioid products?
8 9	efficiencies in the work that we're doing. It's utilizing, you know, teams such as a team in India to help with more administrative tasks in terms of data entry and things like that,	8 9	post-approval change supplements to the FDA. Q. And does Ranbaxy manufacture, sell or distribute any opioid products? A. Ranbaxy's no longer in business.
8 9 10	efficiencies in the work that we're doing. It's utilizing, you know, teams such as a team in India to help with more administrative tasks in terms of data entry and things like that, lowering cost bases in the US.	8 9 10	post-approval change supplements to the FDA. Q. And does Ranbaxy manufacture, sell or distribute any opioid products? A. Ranbaxy's no longer in business. They were bought by Sun Pharmaceuticals. So I
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8 9 10 11 12 13 14 15 16 17 18 19 20	efficiencies in the work that we're doing. It's utilizing, you know, teams such as a team in India to help with more administrative tasks in terms of data entry and things like that, lowering cost bases in the US. Q. And going down, you worked prior to Teva, you joined you were with Ranbaxy. Right? A. Yes. Q. And Ranbaxy manufactures generic drugs, too? A. Yes, they did. Q. And your position was a vice president, regulatory affairs, North America. Correct?	8 9 10 11 12 13 14 15 16 17 18 19 20	post-approval change supplements to the FDA. Q. And does Ranbaxy manufacture, sell or distribute any opioid products? A. Ranbaxy's no longer in business. They were bought by Sun Pharmaceuticals. So I believe when I was there they had some opioid products, but I'm not certain if they still have them or not. Q. What were those opioid products, if you recall? A. I believe it was oxycodone as well. I'm not certain of any others. Q. Did you have any responsibilities with regard to that product, either submitting for approval or regular filings?
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	efficiencies in the work that we're doing. It's utilizing, you know, teams such as a team in India to help with more administrative tasks in terms of data entry and things like that, lowering cost bases in the US. Q. And going down, you worked prior to Teva, you joined you were with Ranbaxy. Right? A. Yes. Q. And Ranbaxy manufactures generic drugs, too? A. Yes, they did. Q. And your position was a vice president, regulatory affairs, North America. Correct?	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	post-approval change supplements to the FDA. Q. And does Ranbaxy manufacture, sell or distribute any opioid products? A. Ranbaxy's no longer in business. They were bought by Sun Pharmaceuticals. So I believe when I was there they had some opioid products, but I'm not certain if they still have them or not. Q. What were those opioid products, if you recall? A. I believe it was oxycodone as well. I'm not certain of any others. Q. Did you have any responsibilities with regard to that product, either submitting for approval or regular filings?

	Page 57		Page 58
1	and submissions to the FDA.	1	sell or distribute opioid products?
2	Q. And when were they bought out by	2	A. No. McNeil Consumer Healthcare
3	Sun?	3	is the over-the-counter division of Johnson &
4	A. I'd say roughly 2015.	4	Johnson.
5	Q. And you left in June of 2013.	5	Q. And before that, you were with
6	Why did you leave for Teva?	6	Ranbaxy again as director of regulatory.
7	A. It was really a growth	7	Correct?
8	opportunity for my career.	8	A. Yes.
9	Q. And were you recruited by Teva?	9	Q. Any responsibility during this
10	A. A headhunter had called me.	10	period for opioid products?
11	Q. Do you have any plans of leaving	11	A. I'm not certain when those
12	Teva right now?	12	submissions were done. It's possible.
13	A. No.	13	Q. And your background, educational
14	Q. And then it looks like you were	14	background, is you went to Temple.
	senior director of regulatory at Ranbaxy from	15	Is MS a master's of science,
15 16	December of '09 to February 2011. Correct?	16	QA/RA?
17	A. Yes.	17	A. Yes, that's correct.
18		18	Q. So you actually had a three-year
	-	19	stint in quality assurance/regulatory affairs as
19 20	McNeil Consumer Healthcare. Right? A. Yes.	20	your educational background. Right?
		21	A. So the program at Temple is a
21	Q. Is that a J&J-related company? A. Yes.	22	master's of science in quality and regulatory
22		23	affairs.
23	Q. And did you have did they,	24	Q. And then your bachelor's degree
24	McNeil Consumer Healthcare, manufacture, market,		Q. And then your bacheror's degree
	Dago E0		5 60
	Page 59		Page 60
1	was bio and chemistry. Correct?	1	the documents that I saw yesterday.
1 2		1 2	
	was bio and chemistry. Correct?		the documents that I saw yesterday.
2	was bio and chemistry. Correct? A. Yes.	2	the documents that I saw yesterday. Q. And are you able to have you
2	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now	2	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday?
2 3 4	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the	2 3 4	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No.
2 3 4 5	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department.	2 3 4 5	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever
2 3 4 5 6	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let	2 3 4 5 6	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of
2 3 4 5 6 7	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let	2 3 4 5 6 7	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and
2 3 4 5 6 7 8	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let me let's do 306. We'll mark the next exhibit.	2 3 4 5 6 7 8	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and have a list run for you of those products?
2 3 4 5 6 7 8	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let me let's do 306. We'll mark the next exhibit.	2 3 4 5 6 7 8 9	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and have a list run for you of those products? A. No.
2 3 4 5 6 7 8 9	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let me let's do 306. We'll mark the next exhibit. (Deposition Exhibit No. Teva-Tomsky-2, Teva Opioid Market Share	2 3 4 5 6 7 8 9	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and have a list run for you of those products? A. No. Q. And then you see here a list of
2 3 4 5 6 7 8 9 10	was bio and chemistry. Correct? A. Yes. Q. Let's go back to a question, now that I have a better understanding of the structure of your department. You know, certainly well, let me let's do 306. We'll mark the next exhibit. (Deposition Exhibit No. Teva-Tomsky-2, Teva Opioid Market Share Calculation: All Opioids, Bates stamped	2 3 4 5 6 7 8 9 10	the documents that I saw yesterday. Q. And are you able to have you ever seen one before yesterday? A. No. Q. Are you able to or have you ever had occasion where you wanted to see a listing of products in a certain class, say, opioids, and have a list run for you of those products? A. No. Q. And then you see here a list of various products, some being brand products.
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	Page 61		Page 62
1	document.	1	I'm not sure what that is.
2	MR. CRAWFORD: Other than you saw	2	BY MR. CRAWFORD:
3	it yesterday, so	3	Q. Well, I'll just focus on actually
4	MS. HILLYER: But he's never seen	4	what are in the listed in the chart starting
5	it before.	5	at page 3 of the document.
6	MR. CRAWFORD: He did yesterday.	6	A. Page 3 appear to be generic names
7	BY MR. CRAWFORD:	7	other than Actiq.
8	Q. You did yesterday. Right?	8	Q. Yeah. And Actiq, Fentora and you
9	A. I believe so.	9	mentioned Fioricet, which is on page 5, that's
10	MS. HILLYER: That doesn't	10	those are brands. Right?
11	establish foundation.	11	MS. HILLYER: Objection to form.
12	THE WITNESS: Can you repeat your	12	THE WITNESS: It appears so.
13	question, please?	13	BY MR. CRAWFORD:
14	BY MR. CRAWFORD:	14	Q. And so for these generic drugs
15		15	some are some actually came over from Actavis,
16	Q. Just wondering if that's these are generic opioid products, other than Actiq and	16	right, when they were acquired by the company in
17	Fentora, listed on this page?	17	2016?
18	MS. HILLYER: On the first page?	18	A. Again, I would assume so. I'm
19	MR. CRAWFORD: On all of the	19	not certain. Again, yesterday was the first time
20		20	I saw this document. I've never seen it before
21	pages. MS. HILLYER: Take your time and	21	other than that.
22	look through it.	22	Q. But your understanding is Teva
23	THE WITNESS: I'm not sure if	23	had some of its own generic opioid products prior
24	Fioricet looks like a brand product, too.	24	to Actavis' acquisition. Right?
24	Proficet fooks like a braild product, too.	24	to Actavis acquistion. Right:
	Page 63		Page 64
-1			
1	A. I believe so, yes.	1	MS. HILLYER: Objection to form.
2	A. I believe so, yes.Q. And then when Actavis was	1 2	MS. HILLYER: Objection to form. THE WITNESS: So the way my team
			-
2	Q. And then when Actavis was	2	THE WITNESS: So the way my team
2	Q. And then when Actavis was purchased, the generic Actavis/Watson entities,	2	THE WITNESS: So the way my team is set up, it's set up by manufacturing
2 3 4	Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid	2 3 4	THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form.
2 3 4 5	Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid products in its portfolio. Correct?	2 3 4 5	THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form. BY MR. CRAWFORD:
2 3 4 5 6	Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid products in its portfolio. Correct? A. Yes.	2 3 4 5 6	THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form. BY MR. CRAWFORD: Q. So if a generic is coming out
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid products in its portfolio. Correct? A. Yes. Q. So those new products were basically came within the purview of your department to ensure that the proper submissions were made at some point. Right? A. Yes. Q. To the FDA? A. Yes. Q. And what I want to know is so there are ongoing submissions required for all your generic products to the FDA, annual reports and the like. Right? A. Yes. Q. And is there any how is that responsibility divided up within your regulatory department? Are certain individuals given kind of responsibility for making sure those	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form. BY MR. CRAWFORD: Q. So if a generic is coming out a generic product is coming out of a certain manufacturing site, how is that responsibility allocated? Is one of the sites Salt Lake City? Is that a manufacturing site for the company? A. Yes. Q. So, for example, if a product is coming out of Salt Lake City, being manufactured there, how is the responsibility for submitting ongoing reports and information to the FDA, how is that allocated or assigned? A. So I have a team in Salt Lake City that manufactures products that are developed there and that manages products that are developed there and manufactured there.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And then when Actavis was purchased, the generic Actavis/Watson entities, Teva then now had some new generic opioid products in its portfolio. Correct? A. Yes. Q. So those new products were basically came within the purview of your department to ensure that the proper submissions were made at some point. Right? A. Yes. Q. To the FDA? A. Yes. Q. And what I want to know is so there are ongoing submissions required for all your generic products to the FDA, annual reports and the like. Right? A. Yes. Q. And is there any how is that responsibility divided up within your regulatory department? Are certain individuals given kind of responsibility for making sure those	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	THE WITNESS: So the way my team is set up, it's set up by manufacturing site or location and also by dosage form. BY MR. CRAWFORD: Q. So if a generic is coming out a generic product is coming out of a certain manufacturing site, how is that responsibility allocated? Is one of the sites Salt Lake City? Is that a manufacturing site for the company? A. Yes. Q. So, for example, if a product is coming out of Salt Lake City, being manufactured there, how is the responsibility for submitting ongoing reports and information to the FDA, how is that allocated or assigned? A. So I have a team in Salt Lake City that manufactures products that are developed there and that manages products that are developed there and manufactured there. Q. And is there somebody in Salt Lake City responsible for putting together the

	Page 65		Page 66
1	A. Yes.	1	That's a team member that's been assigned that
2	Q. And is this a person that is	2	product.
3	physically based in that location?	3	Q. Does Teva have a manufacturing
4	A. Yes.	4	facility in Irvine, California?
5	Q. And is it somebody who's part of	5	A. Yes.
6	your regulatory department?	6	Q. Is there a regulatory team there
7	A. Yes.	7	as well?
8	Q. And who is that for Salt Lake	8	A. Yes. There's two people there.
9	City?	9	Q. Who are they?
10	A. The person who reports to me in	10	A. Eric Sullivan and Joshua Childs.
11	Salt Lake City, her name is Cherri Petrie, it's	11	Q. And do they do the same thing,
12	C-H-E-R-R-I.	12	same process you described for Salt Lake City?
13	Q. And then when she prepares or	13	A. Yes.
14	I don't want to say it that way, strike that.	14	Q. And do they report to you?
15	Is she the one who signs the	15	A. So they report to a person on my
16	annual reports for the drugs out of that	16	team.
17	facility?	17	Q. And who is that?
18	A. So no. Again, as we had covered	18	A. Anil Sachdeva.
19	earlier, many of the annual reports now are done	19	Q. How do you spell that?
20	by a team in Mumbai.	20	A. Last name is S-A-C-H-D-E-V-A.
21	Q. Right.	21	Q. And he's located in Horsham?
22	A. So for annual reports, the team	22	A. He's in Parsippany.
23	in Mumbai would work on those. If they had any	23	Q. Is there any plan to move the
24	question, they would go to Cherri or her team.	24	Horsham folks to Parsippany?
	Page 67		Page 68
1	A. Yes.	1	Q. Prior to the break, you were
2	Q. And when is that supposed to be	2	talking about personnel that were located in Salt
3	completed?	3	Lake City and Irvine, regulatory personnel who
4	A. August 2019.	4	were responsible for some aspect of the FDA
5	Q. Is that where you're going to be	5	reporting regarding products manufactured at
6	located?	6	those sites. Right?
7	A. I'll be located in Parsippany.	7	A. Yes.
8	Q. Any plans to move physically your	8	Q. And also too you talked prior to
9	residence?	9	that about a manufacturing site in Israel that
10	A. No.	10	you interface with some people with. Right?
11	MS. HILLYER: We've been going	11	A. Yes.
12	about an hour.	12	Q. Was it the same type of function,
13	MR. CRAWFORD: Take a little	13	where they were in charge of certain submissions
14	break if you want.	14	that would be made to the FDA with regard to
15	MS. HILLYER: Yeah.	15	products manufactured at those sites?
16	THE VIDEOGRAPHER: Off the	16	A. Yes. They would help coordinate
17	record, 10:28.	17	documents from those sites related to those
18		18	products that were manufactured at those
19	(A recess was taken from	19	locations.
20	10:28 a m. to 10:44 a m.)	20	Q. And do you know where the
21		21	locations are in Israel?
22	THE VIDEOGRAPHER: We are back on	22	A. Kfar Sava, Israel, and Jerusalem.
23	the record at 10:44.	23	Q. How do you spell Kfar Sava?
			· · · · · · · · · · · · · · · · · · ·
24	BY MR. CRAWFORD:	24	A. It's K-F-A-R, S-A-V-A.

	Page 69		Page 70
1	Q. And are those do you know what	1	A. TAPI will sell API to many
2	company owns those sites?	2	companies.
3	A. I'm not sure of the legal entity.	3	Q. Including Teva?
4	Q. Have you ever heard of the name	4	A. Yes.
5	TAPI, T-A-P-I?	5	MR. CRAWFORD: We'll mark the
6	A. Yes.	6	next document here.
7	Q. Is that one of the manufacturing	7	next document here.
8	sites?	8	(Deposition Exhibit No.
9	A. No, that's an API division of	9	Teva-Tomsky-3, Organization Charts, Bates
10	Teva. It's T is Teva, API is active	10	stamped TEVA_MDL_A_03486562 through
11		11	
12	pharmaceutical ingredient. So it's called TAPI.	12	TEVA_MDL_A_03486593, was marked for identification.)
	Q. And just for the jury here, what	13	identification.)
13	is an active pharmaceutical ingredient? What are		DV MD, CDAWEODD.
14	they making?	14	BY MR. CRAWFORD:
15	A. So an active pharmaceutical	15	Q. So we've marked a series of org
16	ingredient is the drug substance. So it's the	16	charts here.
17	active ingredient in a product formulation.	17	Have you ever seen this document?
18	Q. And so then and that's a Teva	18	A. Yes.
19	entity, TAPI. Right?	19	Q. And when did you last see it?
20	A. Yes.	20	A. I don't recall.
21	Q. And then that ingredient is	21	Q. And this is dated July 8, 2013.
22	supplied to the other Teva manufacturing	22	That's about the time you arrived
23	facilities that then formulate the actual	23	at the company. Right?
24	product?	24	A. Yes.
	D 61		
	Page 71		Page 72
1	Q. And does this look like,	1	Q. And he's no longer with the
2	Q. And does this look like, scanning, to you generally what the structure of	2	Q. And he's no longer with the company. Right?
2 3	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs	2 3	Q. And he's no longer with the company. Right? A. That's correct.
2 3 4	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time?	2 3 4	Q. And he's no longer with the company. Right?A. That's correct.Q. Who replaced him?
2 3 4 5	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes.	2 3 4 5	Q. And he's no longer with the company. Right?A. That's correct.Q. Who replaced him?A. Michael Banks.
2 3 4 5 6	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references	2 3 4 5 6	 Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to
2 3 4 5 6 7	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references James G. Ottinger, a senior vice president of	2 3 4 5 6 7	Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to Michael Banks then?
2 3 4 5 6 7 8	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references James G. Ottinger, a senior vice president of regulatory affairs, and under him is Michael	2 3 4 5 6 7 8	Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to Michael Banks then? A. Yes.
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2 3 4 5 6 7 8 9 10 11	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references James G. Ottinger, a senior vice president of regulatory affairs, and under him is Michael Banks, vice president, global generics and OTC. Mr. Banks, you had testified, is your current direct boss. Right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12	Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to Michael Banks then? A. Yes. Q. Did anyone fill Michael Banks' position? A. No. Q. Mr. Banks is in the UK. Right?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references James G. Ottinger, a senior vice president of regulatory affairs, and under him is Michael Banks, vice president, global generics and OTC. Mr. Banks, you had testified, is your current direct boss. Right? A. Yes. Q. And then according to this chart he reported at this time to Mr. Ottinger. Right? A. Yes. Q. Where was Mr. Ottinger physically located? A. In Frazer, Pennsylvania. Q. And do you know who employed him,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to Michael Banks then? A. Yes. Q. Did anyone fill Michael Banks' position? A. No. Q. Mr. Banks is in the UK. Right? A. Yes. Q. Then below that, below Mr. Banks, you have Gary Buehler, vice president, global regulatory intelligence and policy. Do you know Mr. Buehler?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And does this look like, scanning, to you generally what the structure of the regulatory various regulatory affairs departments were at Teva at the time? A. Yes. Q. And the first page references James G. Ottinger, a senior vice president of regulatory affairs, and under him is Michael Banks, vice president, global generics and OTC. Mr. Banks, you had testified, is your current direct boss. Right? A. Yes. Q. And then according to this chart he reported at this time to Mr. Ottinger. Right? A. Yes. Q. Where was Mr. Ottinger physically located? A. In Frazer, Pennsylvania. Q. And do you know who employed him, who his employer was? A. I don't know the legal entity. Q. And did you ever have a chance to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And he's no longer with the company. Right? A. That's correct. Q. Who replaced him? A. Michael Banks. Q. And you still report directly to Michael Banks then? A. Yes. Q. Did anyone fill Michael Banks' position? A. No. Q. Mr. Banks is in the UK. Right? A. Yes. Q. Then below that, below Mr. Banks, you have Gary Buehler, vice president, global regulatory intelligence and policy. Do you know Mr. Buehler? A. Yes. Q. Where he is located? A. He's retired. Q. All right. When did he retire, about?

	Page 73		Page 74
1	position?	1	run when you arrived and currently.
2	A. Not within regulatory.	2	Do you know how the
3	Q. How about another department?	3	pharmacovigilance was run prior to your arrival?
4	A. His responsibilities were kind of	4	A. Can you be more specific?
5	split up. We went through a restructuring, so	5	Q. Let's say prior to 2009 Teva
6	some of those activities are being done now by	6	acquired Cephalon in 2009. Correct?
7	the legal team.	7	MS. HILLYER: Objection to form,
8	Q. And what is it says he was	8	assumes facts not in evidence.
9	global regulatory intelligence and policy.	9	THE WITNESS: Yeah. I'm not
10	What did that position entail?	10	certain of the date of that acquisition.
11	A. It's just collecting information,	11	BY MR. CRAWFORD:
12	new regulations, new policies that regulators	12	Q. How about prior to 2010, do you
13	were looking at. He had a strong focus on the US	13	know how the pharmacovigilance was run?
14	because he was formerly the head of the Office of	14	A. No.
15	Generic Drugs.	15	Q. How about the REMS approval
16		16	process, say, prior to your arrival, how was that
17	Q. With the FDA. Right? A. Yes.	17	run?
18 19	Q. Do you know when he joined the company?	18 19	A. I think we talked about earlier, I'm not certain how it was operated. It was part
		20	of the commercial team.
20			
21	Q. And then going back, just a few	21	Q. I said approval. Okay. I said
22	things.	22	approval process.
23	Were you we talked about	23	I mean REMS, you know,
24	pharmacovigilance and how that how that was	24	compliance.
	Page 75		Page 76
1	MS. HILLYER: Objection to form.	1	from the manufacturing sites and preparing the
2	BY MR. CRAWFORD:	2	annual reports, and then making the submissions
3			
	Q. Do you know how that was run	3	to the FDA.
4	Q. Do you know how that was run prior to your arrival?	3 4	to the FDA.
4 5	prior to your arrival?		to the FDA.
		4	to the FDA. Q. How far back did that process
5	prior to your arrival? MS. HILLYER: Sorry.	4 5	to the FDA. Q. How far back did that process occur? A. I'm not certain.
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	Page 77		Page 78
1	has any responsibility?	1	reports that the regulatory affairs team does,
2	Q. Correct.	2	but I'm sure Teva has proper processes in place
3	A. Yeah. Regulatory has no	3	to do that sort of thing.
4	responsibility, so I'm not aware. For the	4	Q. How do you know they have proper
5	suspicious monitoring or even	5	processes?
6	Q. Is there any regulatory	6	A. I mean, Teva takes compliance
7	requirement for opioids to report information to	7	very seriously. So I mean
8	the FDA about its suspicious order monitoring	8	Q. Do you have personal knowledge
9	program or interactions with the DEA?	9	that they're complying with all the processes?
10	MS. HILLYER: Objection to form	10	A. I mean, again, it's outside the
11	and to the extent it calls for	11	scope of regulatory, so I'm not involved in those
12	speculation.	12	things.
13	THE WITNESS: Yeah. I'm not	13	Q. So you're just making an
14	familiar with the process. It's outside	14	assumption?
15	of the scope of regulatory.	15	MS. HILLYER: Objection to form.
16	BY MR. CRAWFORD:	16	THE WITNESS: No. I'm saying
17	Q. Right. But I'm just wondering,	17	that Teva is a company that is strong on
18	as far as your interactions with the FDA, say in	18	compliance. We all have to do compliance
19	annual reports or anything like that, are you	19	training. And so I don't see how the
20	required to report or do you report to the FDA	20	company wouldn't comply with those
21	any of your interactions with the DEA or	21	regulations or requirements either.
22	suspicious order monitoring activities?	22	BY MR. CRAWFORD:
23	A. So none of that information is	23	Q. Do you mean currently or in the
24	reported to the FDA in the drug product annual	24	past or both?
			Page 80
1		1	
1	A. It's always been a core value of	1	Q. Was there a brand VP for US at
2	A. It's always been a core value of Teva, to maintain compliance.	2	Q. Was there a brand VP for US at this time?
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	Page 81		Page 82
1	Q. At this time, was she in the US?	1	regulatory team that was located in Croatia.
2	A. She was in the US.	2	Q. And who had responsibility for,
3	Q. So looking at page 2, you've	3	say, the non-US or non-North America, non-Europe
4	got your structure is there's one US person	4	regulatory at this time?
5	here, and that's you. Correct?	5	A. If you look further down, it's
6	A. Yes.	6	Iris Meisner, international regulatory affairs.
7	Q. In this structure at this level.	7	Q. Got it. Okay.
8	Right?	8	And who had charge of Canada at
9	A. Yes.	9	this time?
10	Q. Okay. And then you've got	10	
11	Roussell, Braeuner, Baader, Monvoisin, Spilsbury,		A. There was another individual, Mathi Mathivanan. And I believe at that time
12	* *	11	
	they are EU heads or directors or managers in	12	actually, I'm not sure. I'm not certain if he
13	this chart. Right?	13	was where he was reporting into.
14	A. Yes.	14	I think was reporting no. He
15	Q. And are they do they they	15	was. He was reporting into the Canadian business
16	also report to Mr. Banks. Correct?	16	at that time.
17	A. They did at this time.	17	Q. Is there who is in charge of
18	Q. At this time.	18	Canada now at your level?
19	And then and then over on the	19	A. I am.
20	left, there's Alenka Lasic-Gasparevic, senior	20	Q. All right. So you so that's
21	director, global RA.	21	dealing with Canadian regulatory authority
22	Would she be have been in	22	submissions. Right?
23	charge of the non-EU, non-US areas?	23	A. Yes.
24	A. Generally speaking, she led the	24	Q. And why are you in charge in
	Page 83		Page 84
1	Canada?	1	Does she have any do you
2	A. As a part of the restructuring	2	interface with her or does she have any
3	with Actavis, it may have even happened prior to	3	responsibility with regard to the US operations?
4	Actavis, I was given responsibility for not only	4	MS. HILLYER: Objection to form,
5	US generics but also Canadian generics.	5	compound.
6	Q. Are you in charge of any other	6	BY MR. CRAWFORD:
7	countries?	7	Q. Is her department or anything
8	A. No.	8	like that?
9	Q. Who reports to you, directly	9	A. Sorry, can you repeat the
10	under you with regard to Canada?	10	question?
11	A. Mathi Mathivanan.	11	Q. Just trying to find out, her
12	Q. And he's in Canada?	12	department or she have any responsibilities with
13	A. Yes.	13	regard to the US regulatory operations?
14	Q. What city?	14	A. Are you now or are you asking
15	A. Toronto.	15	back in 2013?
16	Q. And briefly, who's the Canadian	16	Q. Back then.
17	regulatory authority?	17	A. So back then, she would have
18	A. Health Canada.	18	managed any regulatory team that was in Zagreb,
19	Q. Go to the next page. That's	19	Croatia. And if there was products that were
20	Alenka.	20	developed there or manufactured there that were
21	Is that a female, Alenka?	21	coming to the US, her team would have compiled
22	A. Yes.	22	documents and sent them to my team.
23	Q. Okay. Lasic-Gasparevic in	23	Q. Similar to Salt Lake City and
	- · · · · · · · · · · · · · · · · · · ·		
24	Zagreb, senior director, global RA.	24	Irvine and Israel?

	Page 85		Page 86
1	A. A little similar, yes.	1	Q. When did he leave?
2	Q. Next. My Bates numbers are cut	2	A. Roughly 2015.
3	off here, so I'm going to try to direct you to	3	Q. And do you know where he is now
4	the correct page on that.	4	working?
5	Would like to go to page 8 with	5	A. I'm not certain.
6	Iris	6	Q. Where was he based?
7	MS. HILLYER: Just give a Bates?	7	A. He was based in Horsham,
8	MR. CRAWFORD: Yeah. My	8	Pennsylvania.
9	colleague can do that here.	9	Q. And he was legacy Teva. He was
10	MR. JENSEN: Bates ending in 569.	10	there when you arrived. Right?
11	BY MR. CRAWFORD:	11	A. Yes.
12	Q. Now, she was you had mentioned	12	Q. And do you know how far back or
13	she was your counterpart for the rest of the	13	how long he'd worked there?
14	world. Right?	14	A. I believe more than 20 years.
15	MS. HILLYER: Objection to form.	15	Actually, it was more than 20 years.
16	THE WITNESS: Yes.	16	Q. Do you know if he's retired?
17	BY MR. CRAWFORD:	17	A. I'm not certain.
18	Q. I think we can move on to page 9.	18	Q. Do you know why he left?
19	This is you right here, under	19	A. His position with the
20	regulatory affairs. And you have Phil Erickson	20	reorganization was no longer needed.
21	below you and Pat Jaworski.	21	Q. Now, Teva's cut jobs worldwide
22	Is Mr. Erickson, is he still with	22	pretty significantly in the last couple years.
23	the company?	23	Right?
24	A. No.	24	A. Yes.
	Page 87		Page 88
1		1	
1 2	Q. And are those layoffs completed	1 2	Page 88 MR. JENSEN: Bates 571. BY MR. CRAWFORD:
	Q. And are those layoffs completed yet or are they still ongoing?		MR. JENSEN: Bates 571. BY MR. CRAWFORD:
2	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form.	2	MR. JENSEN: Bates 571. BY MR. CRAWFORD:
2 3	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form. THE WITNESS: Most of them are	2 3	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571?
2 3 4	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form.	2 3 4	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571? A. Yes.
2 3 4 5	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form. THE WITNESS: Most of them are completed.	2 3 4 5	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571? A. Yes. Q. And Jill Pastore is down there on
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2 3 4 5 6 7	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form. THE WITNESS: Most of them are completed. BY MR. CRAWFORD: Q. And that was about 14,000	2 3 4 5 6 7	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571? A. Yes. Q. And Jill Pastore is down there on the lower right. Is she she was a director. Is that her current position?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form. THE WITNESS: Most of them are completed. BY MR. CRAWFORD: Q. And that was about 14,000 employees worldwide? A. Roughly. Q. What was Mr. Erickson's role at this time? What were his duties? And if you go to the next page, I believe there's a tree underneath him. A. Okay. Q. So if you could describe his duties at this time. A. So at this time, there was two regulatory affairs teams. There was one in Horsham, Pennsylvania for the US generics, and there was one in Woodcliff Lake, New Jersey for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571? A. Yes. Q. And Jill Pastore is down there on the lower right. Is she she was a director. Is that her current position? A. Currently she is senior director. Q. And what is her job now? What are her duties? A. So she is senior director of commercial regulatory and regulatory affairs launch preparedness, it's called. Q. And what does that involve? A. So she oversees the team in Mumbai who prepares the annual reports. And her team also manages tracking of various things, approvals, generic drug user fee dates, submissions that go into the FDA. She also has responsibility for the labeling team and the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And are those layoffs completed yet or are they still ongoing? MS. HILLYER: Objection to form. THE WITNESS: Most of them are completed. BY MR. CRAWFORD: Q. And that was about 14,000 employees worldwide? A. Roughly. Q. What was Mr. Erickson's role at this time? What were his duties? And if you go to the next page, I believe there's a tree underneath him. A. Okay. Q. So if you could describe his duties at this time. A. So at this time, there was two regulatory affairs teams. There was one in Horsham, Pennsylvania for the US generics, and there was one in Woodcliff Lake, New Jersey for US generics. So Phil was managing the team that	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. JENSEN: Bates 571. BY MR. CRAWFORD: Q 571? A. Yes. Q. And Jill Pastore is down there on the lower right. Is she she was a director. Is that her current position? A. Currently she is senior director. Q. And what is her job now? What are her duties? A. So she is senior director of commercial regulatory and regulatory affairs launch preparedness, it's called. Q. And what does that involve? A. So she oversees the team in Mumbai who prepares the annual reports. And her team also manages tracking of various things, approvals, generic drug user fee dates, submissions that go into the FDA. She also has responsibility for the labeling team and the artwork management team.
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	Page 89		Page 90
1	earlier. They monitor the FDA's website, they	1	reporting?
2	prepare labeling to support the US generic	2	A. So the way the team was set up is
3	products.	3	a subset of applications that more or less the
4	Q. And there's Siva Vaithiyalingam,	4	legacy Teva applications were managed through
5	who is a director under Mr. Erickson.	5	this team here. And he oversaw this team.
6	Where is she located at the time?	6	Q. Did that include opioid products?
7	A. It's a he, actually. And he was	7	A. It would include all products.
8	located in Horsham, Pennsylvania.	8	It's possible yes. So Teva the legacy Teva
9	Q. What was his function?	9	opioid products would have been a subset of this
10	A. He was I believe at this time,	10	group.
11	he was he was overseeing all submissions that	11	Q. Okay. And going to the next
12	went to FDA. He's a former FDAer, so he was	12	page, Pat Jaworski, was Pat a male or female?
13	doing he was performing a quality review of	13	A. It's a woman.
14	the applications before they went in, trying to	14	Q. Woman.
15	identify any questions that he had, since he was	15	What was her responsibility?
16	a former FDA reviewer.	16	A. So she was responsible for the
17	Q. And then over on his level, Rob	17	regulatory affairs team that was located in
18	Vincent, senior director, what was his position	18	Woodcliff Lake, New Jersey that supported the US
19	or what did that entail?	19	generics submissions. These are primarily the
20	A. At that time, he was overseeing,	20	legacy Barr and Ivax applications.
21	you know, many of the products that were being	21	Q. So that would mean she I mean,
22	managed by the team in Horsham.	22	what would she do with regard to those legacy
23	Q. What does that mean, managed by	23	drugs? Just oversee the ongoing submissions to
24	the team? Just approvals, ongoing compliance or	24	the FDA?
	Page 91		Page 92
1	A. Yeah. Again, her team would have	1	Booth-Genthe at the top.
2			
_	oversaw the regulatory affairs responsibility in	2	MR. CRAWFORD: Yeah.
3	terms of submissions of new applications as well	2 3	MR. CRAWFORD: Yeah. MS. HILLYER: Ending 582?
3	terms of submissions of new applications as well as maintenance of the approved applications. Q. And Barr and Ivax were two	3	MS. HILLYER: Ending 582? MR. JENSEN: Correct. BY MR. CRAWFORD:
3 4	terms of submissions of new applications as well as maintenance of the approved applications.	3 4	MS. HILLYER: Ending 582? MR. JENSEN: Correct. BY MR. CRAWFORD: Q. Yeah. We'll go through these
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3 4 5 6 7 8	terms of submissions of new applications as well as maintenance of the approved applications. Q. And Barr and Ivax were two companies acquired by Teva back in the middish 2000s? A. I'm not sure when they were	3 4 5 6 7 8	MS. HILLYER: Ending 582? MR. JENSEN: Correct. BY MR. CRAWFORD: Q. Yeah. We'll go through these final tabbed pages. Is Terri a male or a female?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	terms of submissions of new applications as well as maintenance of the approved applications. Q. And Barr and Ivax were two companies acquired by Teva back in the middish 2000s? A. I'm not sure when they were acquired, but yes. Q. Ms. Jaworski, is she still with the company? A. She is not. Q. Okay. How about Mr. Vincent? A. I'm sorry? Q. Mr. Vincent A. So you're going back to the previous page? Q. Yeah. Is he still with the company? A. He is not. Q. Let's go to and I'm not quite	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. HILLYER: Ending 582? MR. JENSEN: Correct. BY MR. CRAWFORD: Q. Yeah. We'll go through these final tabbed pages. Is Terri a male or a female? A. She's a woman. Q. Okay. And did we talk about her previously? I'm slipping memory on the names here. A. No. Q. What is global regulatory operations? What's that function? A. So this is the team that primarily manages all the electronic submissions to the FDA. Q. And how about other regulatory authorities for other countries? A. Yes.
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	Page 93		Page 94
1	Frazer, Pennsylvania.	1	what was submitted?
2	Q. Where is she right now, is she	2	A. It was also managing databases
3	with the company?	3	and things like that.
4	A. She is not with Teva.	4	Q. What kind of databases?
5	Q. Do you know who she's with right	5	Pharmacovigilance?
6	now?	6	A. No. It was the regulatory
7	A. I do not.	7	affairs database.
8	Q. Then go to the next page, we have	8	O. And what's in that database that
9	Javier Monvoisin, head of regulatory information	9	you recall?
10	management.	10	A. Global submission information, US
11	At the time, where was Mr.	11	filings, again, has to do with when the
12	Monvoisin located?	12	submission was submitted to FDA, any responses to
13	A. He was located in the UK.	13	the FDA, details about manufacturers, API
14	Q. Did he or his department perform	14	suppliers, things like that.
15	any functions with regard to the US generic	15	Q. So if you wanted a report, you
16	drugs?	16	know, listing all the opioids and ANDA numbers
17	A. Yes.	17	from your generic opioids, would that be the
18	Q. And what were those functions?	18	person you would go to? Or that department back
19	A. Again, it was submissions,	19	then?
20	electronic submissions to the FDA as well as	20	A. No.
21	other groups.	21	Q. Where would you go for that?
22	Q. So just coordinating getting the	22	A. My team would manage separate
23	documents electronically submitted, or did they	23	spreadsheets for submissions for the FDA.
24	have any role in the substantive preparation of	24	Q. And where would they get their
	J 1 1	24	Q. And where would they get their
	Page 95		Page 96
1	information from for that?	1	Q. Okay. Next is the next page,
2	A. They would generate them	2	Jean Zwicker, is it a female?
3	themselves. It was basically kept in Excel. And	3	A. I'm sorry?
4	it just tracked all submissions and submissions	4	Q. Is she female?
5	that were pending review with FDA, submissions	5	A. Yes.
6	that were approved, applications that were	6	Q. Jean Zwicker, senior director,
7	approved. It was too difficult to get	7	GRA, that's global regulatory affairs. Correct?
8	information out of the global regulatory affairs	8	A. Yes.
9	database. So that was more for the global team	9	Q. Compliance and administration.
10	to have, but it wasn't really for the US region	10	Did she or her department have
11	to have.	11	any function or role with regard to the US
12	Q. The next page, Karen Kulagowska,	12	operations for generics?
13	head of planning, metrics and reporting, what was	13	A. Yes.
1 1 1	her function back then?	14	Q. And what was her role in this
14	A Congain at this time also	15	department at this time?
15	A. So again, at this time, she		
	collected information from each of the different	16	A. It would audit to make sure that,
15		16 17	for example, annual reports were being submitted
15 16	collected information from each of the different		·
15 16 17	collected information from each of the different regions with respect to what submissions went	17	for example, annual reports were being submitted
15 16 17 18	collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what	17 18	for example, annual reports were being submitted to the FDA in accordance with the regulations,
15 16 17 18 19	collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what applications were approved.	17 18 19	for example, annual reports were being submitted to the FDA in accordance with the regulations, that labeling was being updated in accordance
15 16 17 18 19 20	collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what applications were approved. Q. And where was she based?	17 18 19 20	for example, annual reports were being submitted to the FDA in accordance with the regulations, that labeling was being updated in accordance with the regulations to the FDA.
15 16 17 18 19 20 21	collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what applications were approved. Q. And where was she based? A. In the UK.	17 18 19 20 21	for example, annual reports were being submitted to the FDA in accordance with the regulations, that labeling was being updated in accordance with the regulations to the FDA. Q. Would there be was this an
15 16 17 18 19 20 21 22	collected information from each of the different regions with respect to what submissions went into FDA with respect to the US and what applications were approved. Q. And where was she based? A. In the UK. Q. And is she still with the	17 18 19 20 21 22	for example, annual reports were being submitted to the FDA in accordance with the regulations, that labeling was being updated in accordance with the regulations to the FDA. Q. Would there be was this an annual audit or periodic audit that would be

	Page 97		Page 98
1	occurred.	1	does as far as anything that impacts the US?
2	Q. Have you ever seen an audit	2	A. Yes. This is the submission of
3	report generated for your department from this	3	the electronic documents to the FDA.
4	department here?	4	Q. And do you know where
5	A. Yes.	5	generally where these people are located on this
6	Q. And when was the last one you	6	chart?
7	recall seeing?	7	A. If you look to the far left,
8	A. Several years ago.	8	Kevin Tompkins, he was located in Frazer,
9	Q. And where was Ms. Zwicker located	9	Pennsylvania. Ryan Hernandez was in Horsham.
10	at this time?	10	And you can see on here
11	A. Horsham, Pennsylvania.	11	Q. Yeah. Frazer.
12	Q. Horsham.	12	A. Yep.
13	And did she do audits of	13	Q. And Carrie Deming, North America,
14	regulatory affairs departments outside the US?	14	was she in US?
15	A. I'm not certain.	15	A. I'm not sure.
16	Q. Is she still with the company?	16	Q. It says Michael Aviv, associate
17	A. No.	17	director, Israel. Correct?
18	Q. Next page is a senior director,	18	A. Yes.
19	global submissions management.	19	Q. And where was the person these
20	Who eventually it says vacant,	20	three reported to, Tompkins, Deming, Aviv, where
21	but who eventually got this position, do you	21	was that person located?
22	recall?	22	A. I'm not certain.
23	A. I'm not certain.	23	Q. Next page is Jamie Warner, vice
24	Q. Do you know what this department	24	president of global labeling and brand
	Page 99		Page 100
		1	
1	management.	1	with the brand or RLD labels in the US?
1 2	management. Where was again, these are	1 2	
	Where was again, these are		with the brand or RLD labels in the US? A. Yes.
2		2	with the brand or RLD labels in the US? A. Yes.
2	Where was again, these are kind of unisex names, I apologize for having to	2 3	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I
2 3 4 5	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman.	2 3 4	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function?
2 3 4	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman. Q. A woman. Okay.	2 3 4 5	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function? A. No. I mean, she wasn't actively
2 3 4 5 6	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman. Q. A woman. Okay. Is she where is she located at	2 3 4 5 6	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function? A. No. I mean, she wasn't actively doing that. She was overseeing the team.
2 3 4 5 6 7	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman. Q. A woman. Okay. Is she where is she located at this time?	2 3 4 5 6 7	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function? A. No. I mean, she wasn't actively
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2 3 4 5 6 7 8	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman. Q. A woman. Okay. Is she where is she located at this time? A. She was in Frazer, Pennsylvania. Q. What was her role or function?	2 3 4 5 6 7 8	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function? A. No. I mean, she wasn't actively doing that. She was overseeing the team. Q. Right. A. And Jane and Betty here were the ones who were primarily doing that.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Where was again, these are kind of unisex names, I apologize for having to ask this, but is Jamie A. A woman. Q. A woman. Okay. Is she where is she located at this time? A. She was in Frazer, Pennsylvania. Q. What was her role or function? A. Global labeling and brand management. Q. So that would be for not just US labels, but other Teva entities throughout the world. Right? A. Yes. Q. And was part of her function to make sure there was relatively uniform labels across and consistent labels globally? A. Yes. Q. For the Teva products. Right? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	with the brand or RLD labels in the US? A. Yes. Q. Was it her responsibility to I mean ultimate responsibility with regard to that function? A. No. I mean, she wasn't actively doing that. She was overseeing the team. Q. Right. A. And Jane and Betty here were the ones who were primarily doing that. Q. That's Jane Frahn, F-R-A-H-N, and Betty Shieh? A. Yes. Q. And they were just doing the US labels. Right? A. Yes. Q. And Ms. Warner, is she still with the company? A. No. Q. Do you know who has that role right now, kind of overseeing the people that do that?

	Page 101		Page 102
1		1	thing?
1	Q. How about a US role?	1 2	A. Yes.
2	A. Yes.	3	
3	Q. Who is that again? A. Charlene Salmorin.		Q. Then the next page is Betty
4		4	Shieh, manager, generics labeling team. She has the same function of
5	Q. What's her last name? How do you	5	
6 7	spell it? A. S-A-L-M-O-R-I-N.	6	keeping the labels consistent. Right?
8			A. Yes.
9	Q. And then move on about three pages to Jane Frahn.	8	Q. That's all I have on that
10	MR. JENSEN: It's Bates 590.	10	document.
11	BY MR. CRAWFORD:		Let's go to the next one.
12	Q. Ms. Frahn is the woman who was in	11	(Danasitian Erskikit Ma
13	charge at the time of keeping the labels		(Deposition Exhibit No.
14	consistent with the brand or RLD. Right?	13	Teva-Tomsky-4, Email dated 10/28/2015,
15	A. Yes.	14	Bates stamped TEVA_MDL_A_04344415, plus
16	O. And she was based in	15	attachment, 50 pages, was marked for
17	Q. And she was based in Pennsylvania?	16 17	identification.)
18	A. No.		DV MD, CD AWEODD.
19	Q. Where was she based?	18	BY MR. CRAWFORD:
20	A. She was based in Woodcliff Lake,	19	Q. So we've marked
21	New Jersey.	20	TEVA_MDL_A_04344415.
22	•	21	It's an email from James Ottinger
23	Q. Is she still with the company? A. Yes.	22	to Michael Banks, Mr. Tomsky here and others,
24	Q. And does she still do the same	23	dated October 28, 2015. "Subject: FINAL slide
24	Q. And does she still do the same	24	deck for RA work shop."
	Page 103		Page 104
1		1	Page 104 intended for?
1 2	MS. HILLYER: Mark, does the	1 2	intended for?
			intended for? A. I believe this actually, I
2	MS. HILLYER: Mark, does the leads do you know the Bates for the	2	intended for? A. I believe this actually, I know this was used for a meeting that Teva was
2 3	MS. HILLYER: Mark, does the leads do you know the Bates for the attachment?	2 3	intended for? A. I believe this actually, I
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	Page 105		Page 106
1	regulatory affairs team. It didn't discuss plans	1	THE WITNESS: Yeah, I mean, there
2	for restructuring of the team.	2	was again, there was a lot of changes.
3	Q. All right. But after the	3	There is new leadership, you know, from
4	acquisition, the departments, regulatory affairs	4	Actavis that was put in charge of the
5	departments were restructured. Right?	5	global R&D team. And then regulatory
6	A. Yes.	6	moved from reporting into someone who was
7	Q. And is there I couldn't find a	7	legacy Teva to someone who was legacy
8	current org chart or how that's structured, but	8	Actavis.
9	can you generally describe the changes that were	9	And actually, there's been
10	made to the department with the restructuring?	10	several reorganizations since even the
11	A. There were quite a few changes	11	close of the Actavis deal.
12	made to the department, so I'm not certain what	12	BY MR. CRAWFORD:
13	you would like to know.	13	Q. And so who comes to mind that
14	Q. I understand. Yeah.	14	came over from Actavis that's in the current
15	Unfortunately, I could not find anything in the	15	regulatory affairs leadership?
16	document production about the restructuring or	16	MS. HILLYER: Objection to form.
17	what the current structure is.	17	THE WITNESS: So when you say
18	So, you know, I apologize for	18	leadership, what do you mean?
19	asking such a broad question, but I'd just like	19	BY MR. CRAWFORD:
20	to get your kind of what comes into mind as	20	Q. Kind of your position or above.
21	some of the basic, fundamental changes that were	21	A. Currently at my position and
22	made to the department with the Actavis	22	above, I don't believe there's anybody from
23	integration and acquisition?	23	legacy Actavis in regulatory affairs.
24	MS. HILLYER: Objection to form.	24	Q. And I'm talking about, you know,
	Page 107		Page 108
1	we just went through the 2013 chart and we had	1	affairs.
2	all this operations overseas and stuff like that.	2	Q. What is her function or role?
3	Are there any Actavis people	3	A. She manages a portfolio of
4	overseas that are heading up any of the types of	4	products that have to do with the nonsterile,
5	departments that we looked at that you know of?	5	primarily solid oral dosage forms that are
6	MS. HILLYER: Objection to form.	6	manufactured in various sites.
7	THE WITNESS: I'm not certain.	7	Q. And do these include opioid
8	We would need to look at the org charts	8	products?
9	and go by each one.	9	A. Yes, I believe so. Some of them.
10	BY MR. CRAWFORD:	10	Q. And anyone else who comes to mind
11	Q. How about in Pennsylvania and	11	kind of in the positions immediately below you
12	Parsippany, are there any Actavis people kind of	12	from Actavis?
13	in the level immediately below you that you can	13	A. Yes.
14	think of?	14	Q. Who else?
15	A. Yes.	15	A. Janet Vaughn.
16	MS. HILLYER: From legacy	16	Q. What was her last name?
17	Actavis?	17	A. Vaughn.
18	MR. CRAWFORD: Yeah.	18	Q. Janet Vaughn?
19	THE WITNESS: Yes.	19	A. Yes.
20	BY MR. CRAWFORD:	20	Q. V-A-U-G-H-N?
21	Q. And who is that?	21	A. Yes.
22	A. Joyce DelGaudio.	22	Q. And what is her role or function?
23	Q. And she is what position?	23	A. She manages the portfolio of
24	A. Senior director of regulatory	24	products that are handled in the Florida

	Page 109		Page 110
1	manufacturing areas.	1	Salt Lake City?
2	Q. Is she based in Florida or up	2	A. They did. It was on the branded
3	in	3	side, though.
4	A. Sorry?	4	Q. Right. And does that still
5	Q. Where is she based?	5	exist, the branded?
6	A. She's based in Florida.	6	A. I'm not certain. I don't deal
7	Q. Is she out of one of the	7	with it.
8	manufacturing sites down there?	8	Q. But the Salt Lake City site that
9	A. She's at the research and	9	reports to you that we talked about is a generic
10	development site.	10	site that was an Actavis site before the
11	Q. And where's that?	11	acquisition?
12	A. Weston.	12	A. Yes.
13	Q. Anyone else come to mind,	13	Q. And there were certain Actavis
14	Actavis, in a level below you?	14	entities that are the ANDA holders for opioid
15	A. Cherri Petrie.	15	products. Right?
16	Q. And what's her role or function?	16	A. I'm sorry, can you repeat your
17	A. We talked about her before. She	17	question?
18	manages the team in Salt Lake City.	18	Q. Well, when there's an abbreviated
19	Q. Yes.	19	new drug application, there's generally a, what
20	Was Salt Lake City, was that a	20	do you call it, an applicant. Right?
21	Teva site before the acquisition?	21	A. Yes.
22	A. No. This particular site was a	22	Q. Or is there another word for it?
23	legacy Actavis site.	23	A. An applicant.
24	Q. Did Teva have its own site in	24	Q. And I'm just trying to find out
	Daga 111		
	Page 111		Page 112
1		1	
1 2	if there are any you know, what the entities	1 2	Q. How about there are opioids
	if there are any you know, what the entities are that you know of that were the that were		
2	if there are any you know, what the entities	2	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have
2 3	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in	2	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe.
2 3 4	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in for the opioid products?	2 3 4	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe. Q. So the only two facilities that
2 3 4 5	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in for the opioid products? A. I'm not certain who the	2 3 4 5	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe.
2 3 4 5 6	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in for the opioid products? A. I'm not certain who the applicants were for the opioid products. Again,	2 3 4 5 6	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe. Q. So the only two facilities that are manufacturing opioid products that are
2 3 4 5 6 7	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in for the opioid products? A. I'm not certain who the applicants were for the opioid products. Again, Actavis used to file as Watson. They filed as	2 3 4 5 6 7	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe. Q. So the only two facilities that are manufacturing opioid products that are distributed in the US for a Teva-related entity
2 3 4 5 6 7 8	if there are any you know, what the entities are that you know of that were the that were the applicants for the Actavis side that came in for the opioid products? A. I'm not certain who the applicants were for the opioid products. Again, Actavis used to file as Watson. They filed as Actavis Salt Lake City. Some of them were filed	2 3 4 5 6 7 8	Q. How about there are opioids distributed in Europe. Correct? A. I'm not certain. I don't have responsibility for Europe. Q. So the only two facilities that are manufacturing opioid products that are distributed in the US for a Teva-related entity are in Salt Lake City and Florida?
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1 It's got the agenda. 2 And the second bullet point is, 3 "Generics RA Structure and Operating Principles." 4 Michael Banks is global, you're listed for North 5 America, and Jonathan Roussell is for European. 6 Does that mean that you guys were 7 talking at this workshop or that's just 8 identifying people in charge of the structures? 1 RA. 2 Q. And so did Mr. E 3 global? 4 A. Yes. 5 Q. And then shared 6 structure and operating principles. 7 regulatory operations, that's 8 And labeling and brand ma	Banks present on
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6 Does that mean that you guys were 6 structure and operating print talking at this workshop or that's just 7 regulatory operations, that's	services
7 talking at this workshop or that's just 7 regulatory operations, that's	
9 A. I'm not certain I understand your 9 Warner.	magement, that's 1413.
10 question. 10 Did they present a	nt this as well?
11 Q. Did you present or talk at this 11 A. Yes.	w mis as wen.
12 workshop? 12 Q. And shared servi	ices structure
13 A. Yes. 13 what does that mean?	ices siructure,
	y Teva was set up
15 agenda item on this page in relation to your 15 at this time is that there wer	
	, and the second
18 question. 18 would be a shared service for 19 O. Okay. Was there an agenda for 19 teams. So the North Ameri	
[-
20 this workshop? 20 generics team and the global	al regulatory affairs
21 A. This appears to be the agenda. 21 team.	
22 Q. Right. And so what was your role 22 Q. Go to slide 2. Th	
23 in the agenda? 23 kind of a circle of boxes are	
24 A. To present North America generics 24 called "Global Regulatory A	Affairs." The title
Page 115	Page 116
1 is, "Teva Regulatory Affairs Past State and 1 for speculation.	
	S: I think it's clear
3 Can you just describe what this 3 on here what he's sa	
4 slide is trying to convey? 4 generics and brands	-
5 A. Yes. I mean, this was a slide 5 different and he's se	·
6 that would have been presented by Jim Ottinger. 6 areas. So they're se	U 1
	a common leadership,
	ction independently
9 oversight, more or less, for all of these 9 and separately.	r <i></i>
10 different groups. 10 BY MR. CRAWFORD:	
	enerics. Right?
12 (sic) affairs at this time in 2015 based out of? 12 A. Yes.	1454
	nnged now; they're
14 Q. And so again, slide 3 is Mr. 14 combined. Right?	
	: Objection to form.
	S: No. So I would say
transformed the RA function to the following 17 still it's it's still the	· ·
18 overarching principles." 18 mean, it's under one	
19 And he's talking about the, 19 leadership, but there	-
20 skipping down, the shared services and creating a 20 between the two. I	
21 global organization. 21 interact with the bra	
21 global organization. 21 lineract with the ora 22 Was that something that Mr. 22 BY MR. CRAWFORD:	ana group at an.
	reate charad
23 Ottinger felt like he had done with the company? 23 Q. It does say, "c. 24 MS. HILLYER: Objection, calls 24 services."	icale shareu
24 services.	

	Page 117		Page 118
1		1	
1	So are there shared services	1	center of excellence in Israel.
2 3	between the two groups?	2	Q. Do you know what that means, for
	A. So again, yes. Those are the	3	what you know, what was
4 5	shared services that we've previously spoken about and those are the ones that do the	4	A. I think it's stating that it's
6		5	stating that the growth market regulatory
7	submissions to the FDA. It's only the regulatory	6	operations would be managed in Israel.
8	operations that it's a shared service.		Q. Growth market, what does that mean?
9	Labeling the global labeling brand management is no longer a shared service.	8 9	
10		10	A. That means not US, not Europe. It's other countries.
11	Q. Go to slide 4, second bullet		
12	point. It says, "Create centers of excellence for efficiencies and harmonization."	11	Q. Developing type of countries?
13		12	A. Exactly.
14	And then the third bullet point below that is, "Create a GM COE in Israel."	13	Q. Page 8 kind of gives it says,
15	What does that mean?	14	"Today's focus." So it's got Mr. Ottinger at the
		15	top. It has global regulatory affairs. And then
16		16	they're talking about global generics and OTC.
17 18	Q. What does COE stand for, do you know?	17	That's Mr. Banks, your boss.
		18	Right? A. Yes.
19		19	
20	Q. How about GM, global management?A. I'm not certain. I don't know if	20	Q. And global regulatory operations.
22		21 22	I think we talked about that. And then global
23	it's global management or growth markets. I believe, actually it's	23	labeling and brand management. That's Ms.
24	coming back to me. I think it's growth market	24	Warner. Global intelligence and compliance, Terri Stewart.
24	coming back to me. I think it's growth market	24	Tem Stewart.
	Dama 110		
	Page 119		Page 120
1		1	
1 2	I think we talked about Terri	1 2	it shared worldwide or both, or what does that
1 2 3	I think we talked about Terri Stewart.	1 2 3	it shared worldwide or both, or what does that mean?
2	I think we talked about Terri Stewart. Where is she located?	2	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form.
2 3 4	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken	2 3	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared
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2 3 4 5	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she?	2 3 4 5	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD:
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2 3 4 5 6 7	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she?	2 3 4 5 6 7	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance.
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2 3 4 5 6 7 8 9 10 11 12 13	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she? A. It's a she. Q. And where is she located at this time? A. She was in Washington, DC. Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence? A. No. So Mr. Buehler would have	2 3 4 5 6 7 8 9 10 11	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance. You've got senior VP global regulatory affairs. Is that, at this time, Mr. Ottinger, right, as the top of the pyramid? A. Yes. Q. And then the executive leadership
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she? A. It's a she. Q. And where is she located at this time? A. She was in Washington, DC. Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence? A. No. So Mr. Buehler would have retired by now. Q. I see. Is Ms. Stewart still with the company? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance. You've got senior VP global regulatory affairs. Is that, at this time, Mr. Ottinger, right, as the top of the pyramid? A. Yes. Q. And then the executive leadership team, it says, "L3 heads of functional areas (5), plus HR and Finance Business Partners." Were you one of the five heads they're referring to here? A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she? A. It's a she. Q. And where is she located at this time? A. She was in Washington, DC. Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence? A. No. So Mr. Buehler would have retired by now. Q. I see. Is Ms. Stewart still with the company? A. No. Q. Has she been replaced? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance. You've got senior VP global regulatory affairs. Is that, at this time, Mr. Ottinger, right, as the top of the pyramid? A. Yes. Q. And then the executive leadership team, it says, "L3 heads of functional areas (5), plus HR and Finance Business Partners." Were you one of the five heads they're referring to here? A. No. Q. Where do you fall on this pyramid?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she? A. It's a she. Q. And where is she located at this time? A. She was in Washington, DC. Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence? A. No. So Mr. Buehler would have retired by now. Q. I see. Is Ms. Stewart still with the company? A. No. Q. Has she been replaced? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance. You've got senior VP global regulatory affairs. Is that, at this time, Mr. Ottinger, right, as the top of the pyramid? A. Yes. Q. And then the executive leadership team, it says, "L3 heads of functional areas (5), plus HR and Finance Business Partners." Were you one of the five heads they're referring to here? A. No. Q. Where do you fall on this pyramid?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	I think we talked about Terri Stewart. Where is she located? A. So we have not previously spoken about her. Q. Okay. Is it she? A. It's a she. Q. And where is she located at this time? A. She was in Washington, DC. Q. And did Mr. Buehler work underneath her in global intelligence or in intelligence? A. No. So Mr. Buehler would have retired by now. Q. I see. Is Ms. Stewart still with the company? A. No. Q. Has she been replaced? A. No. Q. So what does it mean by regular	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it shared worldwide or both, or what does that mean? MS. HILLYER: Objection to form. THE WITNESS: It was shared between brand, generic and globally. BY MR. CRAWFORD: Q. And then the next page, 9, global regulatory affairs governance. You've got senior VP global regulatory affairs. Is that, at this time, Mr. Ottinger, right, as the top of the pyramid? A. Yes. Q. And then the executive leadership team, it says, "L3 heads of functional areas (5), plus HR and Finance Business Partners." Were you one of the five heads they're referring to here? A. No. Q. Where do you fall on this pyramid? A. Senior leadership team.

	Page 121		Page 122
1	A. If you go back to page 8, it's	1	A. My slides begin on slide 28.
2	those five people that are under James Ottinger.	2	Q. And go till when?
3	O. Got it.	3	A. And go to 42.
4	Susan Franks, global branded	4	Q. Okay. Slide 21, can you I
5	regulatory, where was she located?	5	don't understand this slide. It says, from
6	A. Yes. We spoke about her before.	6	multiple sites, then an arrow to main centers,
7	She was in Frazer, Pennsylvania.	7	and then it has a bunch of you know, looks
8	Q. Go to page 13. It does say	8	like factories there or something. And then two
9	leadership team there.	9	office buildings.
10	Are they talking about the senior	10	Can you describe what this is
11	leadership team in this chart here, from the	11	trying to convey here?
12	chart on 9?	12	A. I didn't prepare this slide.
13	A. This is describing the global	13	If you look at it in conjunction
14	generic and OTC leadership team.	14	with slide 20, it's talking about the growth
15	Q. And are you part of this team?	15	market regulatory affairs team. It appears they
16	A. Yes.	16	were split up between many sites and they created
17	Q. And you're North American	17	two main centers.
18	generics here. Right?	18	Q. Are any of these sites on the
19	A. Yes.	19	left in the US?
20	Q. Go to number page 21.	20	A. I don't believe so.
21	Can you describe what this	21	Q. CA, is that California?
22	chart if you did you make any presentation	22	A. It could be Canada. I'm not
23	off of these slides? Were any of these your	23	certain, though.
24	slides, if you know?	24	Q. Go to page 27.
	Page 123		Page 124
1	It's global GNX, is that	1	0 0 1121 1 1 1
		+	Q. Could it have been the regulatory
2	generics?	2	intelligence function maybe?
3	A. Yes.		intelligence function maybe? MS. HILLYER: Objection.
3 4	A. Yes. Q. And OTC summary.	2	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD:
3 4 5	A. Yes. Q. And OTC summary. OTC is over the counter.	2 3	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department?
3 4 5 6	A. Yes. Q. And OTC summary. OTC is over the counter. Correct?	2 3 4 5 6	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of
3 4 5	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes.	2 3 4 5	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation.
3 4 5 6 7 8	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby,	2 3 4 5 6 7 8	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain.
3 4 5 6 7 8 9	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and	2 3 4 5 6 7 8	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't
3 4 5 6 7 8 9	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental	2 3 4 5 6 7 8 9	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would
3 4 5 6 7 8 9 10	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working	2 3 4 5 6 7 8 9 10	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this.
3 4 5 6 7 8 9 10 11	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet	2 3 4 5 6 7 8 9 10 11	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD:
3 4 5 6 7 8 9 10 11 12	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input	2 3 4 5 6 7 8 9 10 11 12 13	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart,
3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders"	2 3 4 5 6 7 8 9 10 11 12 13 14	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA
3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration	2 3 4 5 6 7 8 9 10 11 12 13 14 15	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA.
3 4 5 6 7 8 9 10 11 12 13 14 15	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's."	2 3 4 5 6 7 8 9 10 11 12 13 14 15	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's." What is HA?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again? A. No.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's." What is HA? A. Health authorities.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again? A. No. Q. Who was in that position?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's." What is HA? A. Health authorities. Q. All right. So what is this a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again? A. No. Q. Who was in that position? A. This is me.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's." What is HA? A. Health authorities. Q. All right. So what is this a function one of the functions of one of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again? A. No. Q. Who was in that position? A. This is me. Q. That's you. Okay.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. And OTC summary. OTC is over the counter. Correct? A. Yes. Q. Looking down, it says, "Lobby, influence and establish Teva access and credibility with Agencies and Governmental Organizations on regulation and policy working closely with Teva Government Affairs." Bullet point, "Working with and coordinating Teva input with all relevant associations and stakeholders" and "Maximise Regional and Global collaboration with HA's." What is HA? A. Health authorities. Q. All right. So what is this a function one of the functions of one of the regulatory department divisions?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	intelligence function maybe? MS. HILLYER: Objection. BY MR. CRAWFORD: Q. Within the regulatory department? MS. HILLYER: Objection, lack of foundation, calls for speculation. THE WITNESS: I'm not certain. The regulatory intelligence group wasn't under him, so I'm not sure why he would have been speaking about this. BY MR. CRAWFORD: Q. Then 29, there's kind of a chart, some type of organizational chart, head, NA generics RA. Is that Mr. Ottinger again? A. No. Q. Who was in that position? A. This is me. Q. That's you. Okay. So these down below is Irvine.
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Page 125 Page 126 1 Q. And how does this Irvine facility 1 having regulatory function in those sites for 2 2 relate to you in this chart? drugs that were sold in the US? 3 3 Because if you see the steriles So not necessarily. 4 products? 4 Right. 5 Yeah. 5 So what this means is that there Q. 6 6 are products that are coming from these sites to A. So those are the sites that 7 support the sterile portfolio of products. 7 the US. There may or may not be regulatory 8 Irvine is one of those sites. That's what I had 8 people at those sites. But if there's not 9 9 mentioned earlier as well. regulatory people at those sites, then there's 10 regulatory people at this time either in 10 Okay. And Haarlem, Zagreb and 11 Horsham -- actually, only in Horsham, 11 Godollo. 12 Pennsylvania, that would work with other 12 Haarlem is in The Netherlands. 13 Right? 13 functions to get the documents for those 14 14 submissions. Yes. 15 Q. Zagreb in Croatia. 15 Q. Got it. 16 16 Page 30, "Regulatory Affairs --Where is Godollo? 17 Godollo is in Bucharest. 17 North American Generics." It says, under the second bullet point, "Compliance was suffering 18 In where? 18 Q. 19 A. Bucharest. 19 under previous models," including "Untimely 20 submission of Annual Reports due to conflicting 20 Bucharest, okay. Romania. 21 So these are manufacturing sites 21 priorities for pre and post." 22 that -- where they had regulatory people that --22 Were you aware of any untimely 23 that made submissions to you or -- sorry. 23 submissions of annual reports that was occurring 24 It's what you described about 24 under Teva's previous model? Page 127 Page 128 1 was becoming a focus area for FDA and a focus Yes. So there was an issue with 1 2 filing annual reports on time. That's what this 2 area for us to ensure that we maintain 3 is discussing. So for FDA, the regulations 3 compliance. 4 require you submit annual reports within 60 days. 4 Q. And was the FDA, was there ever 5 5 And the team was having trouble meeting the any kind of warning or enforcement or 483 6 compliance to submit those annual reports within б observations with regard to Teva in particular 7 7 and its submission of annual reports? 60 days because the teams were not split for 8 pre-approval and post-approval. So they were 8 A. Not that I'm aware. 9 trying to manage all the pre-approval and 9 And wouldn't you feel this 10 post-approval activities on the teams. And with 10 untimely submission was corrected, this issue? 11 priorities, you know, and the thing that suffered 11 Or was it corrected? 12 was filing the annual reports on time. 12 A. It was corrected. It was Q. And that's 60 days from the 13 13 corrected in 2014 time frame. 14 anniversary date? 14 Q. And how was that corrected, by 15 A. Yes. 60 days from the 15 combining the pre and post? 16 anniversary date of the approval. 16 A. So by separating actually the pre 17 Q. And what is the bullet point, 17 and post, and having a dedicated post-approval 18 team that focused on submission of annual "FDA enforcement and 483 observations within 18 19 industry"? What was going on there with 19 reports. 20 compliance suffering under the previous model? 20 Q. And again, who is in charge of 21 A. So I was saying that I was aware 21 the post-submission function? 22 22 of other companies receiving 483 observations A. At that time? 23 from FDA during inspections for not filing annual 23 Just when you reorganized and put 24 reports on time. So that's why I was saying it 24 somebody in charge.

	Page 129		Page 130
1	A. It was several people. At one	1	THE WITNESS: Yes.
2	point I mean, it changed from two to three	2	MR. CRAWFORD: That would be a
3	people.	3	good breaking point then.
4	Q. How about when it was in the	4	Why don't we just mark the next
5	untimely submission phase, who was in charge of	5	two.
6	that?	6	
7	A. It was Robert Vincent. We	7	(Deposition Exhibit No.
8	covered him before on one of the org charts.	8	Teva-Tomsky-5, Email dated 7/27/2017,
9	Q. Right. Thank you.	9	Bates stamped TEVA_MDL_A_09019329 through
10	MR. CRAWFORD: All right. That's	10	TEVA_MDL_A_09019333 and
11	all I have on that.	11	TEVA_MDL_A_09019546 through
12	MS. HILLYER: So we've been going	12	TEVA_MDL_A_09019551, and Deposition
13	about an hour. I was going to try to go	13	Exhibit No. Teva-Tomsky-6, Transmittal of
14	till noon if that would be a good lunch	14	Advertisements and Promotional Labeling
15	breaking spot or	15	for Drugs and Biologics for Human Use,
16	MR. CRAWFORD: Yeah, I think	16	Bates stamped TEVA_MDL_A_04342838 through
17	MS. HILLYER: a quick document	17	TEVA_MDL_A_04342849, were marked for
18	to start	18	identification.)
19	MR. CRAWFORD: Okay. Yeah.	19	
20	Let's try I've got two documents. It	20	BY MR. CRAWFORD:
21	might be pretty quick and then we'll go	21	Q. So we marked Exhibits 5 and 6.
22	into the next section.	22	Let's go to 5 first.
23	MS. HILLYER: Is that okay for	23	That would be it looks like an
24	you?	24	email from Penny Levin to a number of people,
	Page 131		Page 132
1	Page 131 including Mr. Tomsky here, dated July 27, 2017.	1	Page 132 Do you see that?
1 2	including Mr. Tomsky here, dated July 27, 2017.	1 2	Page 132 Do you see that? A. Yes.
	including Mr. Tomsky here, dated July 27, 2017. The subject is "Comments to the		Do you see that? A. Yes.
2	including Mr. Tomsky here, dated July 27, 2017.	2	Do you see that? A. Yes. Q. And are these do these take
2 3	including Mr. Tomsky here, dated July 27, 2017. The subject is "Comments to the Docket FDA Hatch Waxman Amendments." Ms. Levin writes, "Hello All,	2 3	Do you see that? A. Yes.
2 3 4	including Mr. Tomsky here, dated July 27, 2017. The subject is "Comments to the Docket FDA Hatch Waxman Amendments."	2 3 4	Do you see that? A. Yes. Q. And are these do these take place on a pretty regular basis, these global
2 3 4 5	including Mr. Tomsky here, dated July 27, 2017. The subject is "Comments to the Docket FDA Hatch Waxman Amendments." Ms. Levin writes, "Hello All, Below please find the presentations given by	2 3 4 5	Do you see that? A. Yes. Q. And are these do these take place on a pretty regular basis, these global meetings?
2 3 4 5 6	including Mr. Tomsky here, dated July 27, 2017. The subject is "Comments to the Docket FDA Hatch Waxman Amendments." Ms. Levin writes, "Hello All, Below please find the presentations given by Andy, Gregg, and Scott. Also find attached are	2 3 4 5 6	Do you see that? A. Yes. Q. And are these do these take place on a pretty regular basis, these global meetings? MS. HILLYER: Objection to form.
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	Page 133		Page 134
1	again, this is just the standard service	1	charge of bioequivalent studies.
2	that Teva uses for conference calls. It	2	Q. And where was he based?
3	sends out all these numbers for every	3	A. He's currently based in
4	meeting, whether or not there's people in	4	Parsippany, New Jersey.
5	those countries that are calling into the	5	Q. How about at this time, where was
6		6	he based? US?
7	call. But only the people who are	7	
8	invited can call in, will have the access numbers.	8	A. US. Q. Okay. And then he writes, kind
9	BY MR. CRAWFORD:		•
10		9	of about a little over midway through that one
11	Q. I see.	11	sentence paragraph, "The other topic I want to
12	So this was sent out just to the	12	highlight here today is the need for definitive criteria for the approval of generic AD opioids."
13	people on the July 19th 5:20 p m. email to	13	**
14	participate in this. Right?	14	Is that abuse-deterrent opioids?
15	A. Right. Because you never know		A. Yes.
	where any of these people are at any one time.	15	Q. And did you have any involvement
16	They could be traveling in any one of these	16	at all in anything with regard to abuse-deterrent
17	countries and need to dial in and access it. So	17	opioids?
18	that's why the numbers are circulated.	18	MS. HILLYER: Objection to form.
19	Q. I get it.	19 20	THE WITNESS: Can you clarify
20 21	So let's go to a Mr. Gregg	21	your question? BY MR. CRAWFORD:
22	DeRosa's presentation?	22	Q. Are you familiar with
23	What was Mr. DeRosa's position at this time?	23	abuse-deterrent opioids and what they are?
24	A. Generally speaking, he's in	24	A. Yes.
24	A. Generally speaking, he's in	24	A. 165.
	Page 135		Dago 126
1	5		Page 136
1	Q. And did Teva develop any	1	Q. Got it.
1 2		1 2	
	Q. And did Teva develop any		Q. Got it.
2	Q. And did Teva develop any abuse-deterrent opioids?	2	Q. Got it.A. So I had no my team had no
2	Q. And did Teva develop any abuse-deterrent opioids? A. Yes.	2 3	Q. Got it. A. So I had no my team had no responsibility for that.
2 3 4	Q. And did Teva develop any abuse-deterrent opioids?A. Yes.Q. And did they get approval for any	2 3 4	Q. Got it.A. So I had no my team had no responsibility for that.Q. All right. But here they're
2 3 4 5	Q. And did Teva develop any abuse-deterrent opioids?A. Yes.Q. And did they get approval for any abuse-deterrent opioids?	2 3 4 5	Q. Got it. A. So I had no my team had no responsibility for that. Q. All right. But here they're talking about generic abuse-deterrent opioids.
2 3 4 5 6	Q. And did Teva develop any abuse-deterrent opioids? A. Yes. Q. And did they get approval for any abuse-deterrent opioids? A. I'm not certain. I'm on the generic side, I'm not certain. Q. How about brand?	2 3 4 5 6	Q. Got it. A. So I had no my team had no responsibility for that. Q. All right. But here they're talking about generic abuse-deterrent opioids. Was Teva developing generic abuse-deterrent opioids at this time? A. I believe so, yes.
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2 3 4 5 6 7 8 9 10 11	Q. And did Teva develop any abuse-deterrent opioids? A. Yes. Q. And did they get approval for any abuse-deterrent opioids? A. I'm not certain. I'm on the generic side, I'm not certain. Q. How about brand? A. I believe so. Q. And that's Vantrela? A. Yes. Q. And the company decided not to	2 3 4 5 6 7 8 9 10 11	Q. Got it. A. So I had no my team had no responsibility for that. Q. All right. But here they're talking about generic abuse-deterrent opioids. Was Teva developing generic abuse-deterrent opioids at this time? A. I believe so, yes. Q. And had they submitted an application for any abuse-deterrent opioids? A. I believe so, yes. Q. Have any been approved or were
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And did Teva develop any abuse-deterrent opioids? A. Yes. Q. And did they get approval for any abuse-deterrent opioids? A. I'm not certain. I'm on the generic side, I'm not certain. Q. How about brand? A. I believe so. Q. And that's Vantrela? A. Yes. Q. And the company decided not to market Vantrela. Right? A. Yes, that's my understanding. Q. You don't know why they didn't market it? A. I have no idea. Q. But they got approval for it. Right? A. That's my understanding. Q. That was run through your department. Right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Got it. A. So I had no my team had no responsibility for that. Q. All right. But here they're talking about generic abuse-deterrent opioids. Was Teva developing generic abuse-deterrent opioids at this time? A. I believe so, yes. Q. And had they submitted an application for any abuse-deterrent opioids? A. I believe so, yes. Q. Have any been approved or were any approved at this time? A. I'm not certain. Again, we actually, I haven't said this, but we have a huge portfolio of products. I mean, we have more than 1,300 approved applications, we have more than 250 pending applications. So I'm not certain in this time period and even now, honestly, if what's approved and not approved, if it's an abuse-deterrent opioid. Q. Were there any issues with having

Page 137 Page 138 1 issues? 1 page, page 548 is your presentation. Correct? 2 2 A. Yeah, I think FDA continues to A. Yes. It wasn't a presentation. 3 3 update its requirements and regulations. It It was just a talk. 4 publishes guidances on, you know, what is 4 So is this something that you 5 required to be submitted. But there's really a 5 just read into the record when you were at the 6 lack of clarity in terms of what the equivalent 6 meeting? 7 criteria are for these. 7 A. Yes. 8 So I think that's what Gregg is 8 O. And just briefly describe to me 9 discussing in his topic here. 9 what GDUFA II is. 10 Q. So it's like if there's a brand 10 A. GDUFA stands for generic drug 11 and they have an abuse-deterrent property, the user fee amendments. And GDUFA II is the second 11 12 question is, is what are the criteria for a 12 five-year period of the generic drug user fee. 13 generic trying to have a similar abuse deterrent 13 Q. And briefly describe what GDUFA 14 property that would allow it to be approved. 14 is. 15 Is that kind of the issue? 15 A. So GDUFA has to do with the FDA's 16 MS. HILLYER: Objection to form. 16 collection of fees for applications that are 17 THE WITNESS: So FDA requires the 17 submitted for running the generic regulatory 18 generic to behave the same as the brand, 18 process. So FDA receives appropriations from the 19 but it's not certain in terms of, well, 19 government, but then those appropriations are 20 how similar is similar enough. So I 20 supplemented by fees. And it's not only on the 21 think that's what Gregg was talking to in 21 generic side, but the generic user fees are 22 his discussion. 22 fairly new versus the specialty or branded user 23 BY MR. CRAWFORD: 23 fees. 24 Q. All right. And then the next 24 So in exchange for the generics Page 139 Page 140 paying these fees, part of the GDUFA, I don't 1 would reduce the cost of medicines and improve 1 2 know, guidelines or regulations are that FDA has 2 the speed and accuracy of information for 3 certain performance goals as well to speed the 3 patients. These paper labels are a waste of our 4 process along; is that correct? 4 time and resources. More often than not they are 5 A. Right. The fees are to 5 discarded by our customers and never reviewed in 6 supplement appropriations. So FDA agreed to 6 their paper form by their intended audience, 7 review applications within a certain time frame. 7 physicians." 8 And then they could either issue a deficiency or 8 Is that an accurate statement, in 9 an approval, depending on the quality of the 9 your view? 10 information in that filing. 10 A. I'm not certain. 11 Q. And when it was passed, it was a 11 Q. So when Teva ships a product, a 12 five-year timetable. And then GDUFA II means 12 generic product, it generally is shipped to 13 that they were trying to or did get it renewed 13 where, a wholesale distributor or a pharmacy, do you know that end of it? 14 for five years? 14 15 15 A. I'm not involved in that part of A. That's correct. 16 16 it, I'm not certain where it actually goes. O. And was it renewed? 17 Yes. 17 Q. Let's go to Exhibit 6, please. A. Then the last one, presentation, MS. HILLYER: Do you just limit 18 18 Q. 19 is an Andy Boyer. 19 it? Because we're near -- we've been 20 He talks on the second to last 20 going an hour and a quarter. 21 paragraph about "Take" the example -- "for 21 MR. CRAWFORD: Very limited. 22 example the requirement to provide paper labeling 22 Probably less than five minutes. 23 and inserts with our medicines. Modernizing the 23 PHONE SPEAKER: Before we move on 24 labeling regulations to allow for e-labeling 24 to Exhibit 6, could you just tell us the

	Page 141		Page 142
1	Bates number for Exhibit 5?	1	A. It appears so.
2	MR. CRAWFORD: Okay. 5 was	2	Q. And this is somebody signed
3	MS. HILLYER: Well, it's a	3	this, Jamie Warner, it looks like, for you.
4	compilation.	4	Right?
5	MR. CRAWFORD:	5	A. Yeah. So Jamie is the person we
6	TEVA_MDL_A_09019329. And then a portion	6	covered earlier, who is in charge of brand
7	of the attachment to that letter,	7	labeling and management.
8	starting at Bates number, same prefix but	8	Q. Right. Have you signed any of
9	ending with 19546. And then moving to	9	these personally?
10	the end of that document.	10	A. No.
11		11	Q. Why does she sign for you? Why
12	PHONE SPEAKER: Thank you. BY MR. CRAWFORD:	12	doesn't she just sign for her?
		13	A. I have the same question,
13	Q. If I can go briefly on this.	14	honestly. I'm not sure, because I had no
14	So here, this is a "Transmittal	15	involvement in it whatsoever.
15	of Advertisements and Promotional Labeling for	16	
16	Drugs and Biologics for Human Use."	17	Q. So but this is the convention
17	When you have an advertising or		graphic attached to it here that was submitted
18	promotional piece even for generics, you're	18	with this. Right?
19	required, as a company, to submit that to the	19	A. It appears to be.
20	FDA. Correct?	20	Q. And then there's a label for the
21	A. Yes.	21	product as well. Right?
22	Q. And this is a convention graphic	22	A. Yes.
23	for a product hydromorphone HCI injection USP	23	Q. Okay. And on the back of the
24	CII. Correct?	24	label, it says, kind of the second to last
	Page 143		
	rage 143		Page 144
1		1	Page 144 that product primarily, that's who I would go
1 2	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA	1 2	
	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA		that product primarily, that's who I would go
2	paragraph, under "Storage: Protect From Light,"	2	that product primarily, that's who I would go to.
2 3	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by:	2	that product primarily, that's who I would go to. Q. So there are people on your
2 3 4	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured	2 3 4	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are
2 3 4 5	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral MedicinesIrvine,	2 3 4 5	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are these people in your location or are these people
2 3 4 5 6	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral MedicinesIrvine, California."	2 3 4 5 6	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are these people in your location or are these people at the manufacturing site that
2 3 4 5 6 7	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral MedicinesIrvine, California." Do you have any idea why Hospira	2 3 4 5 6 7	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are these people in your location or are these people at the manufacturing site that A. It could be either/or.
2 3 4 5 6 7 8	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral MedicinesIrvine, California." Do you have any idea why Hospira is manufacturing this for Teva Parenteral?	2 3 4 5 6 7 8	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are these people in your location or are these people at the manufacturing site that A. It could be either/or. Q. All right.
2 3 4 5 6 7 8	paragraph, under "Storage: Protect From Light," it says, "A Schedule Class II Narcotic. DEA order form required." It says, "Manufactured by: Hospira, Inc.," but then it says, "Manufactured For: Teva Parenteral MedicinesIrvine, California." Do you have any idea why Hospira is manufacturing this for Teva Parenteral? A. I'm not certain.	2 3 4 5 6 7 8	that product primarily, that's who I would go to. Q. So there are people on your team when you say primarily responsible, are these people in your location or are these people at the manufacturing site that A. It could be either/or. Q. All right. MR. CRAWFORD: That's all I have
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	Page 145		Page 146
1	the record at 12:38.	1	chart in 2013. Right?
2	BY MR. CRAWFORD:	2	A. Yes.
3	Q. Okay. We marked the next	3	Q. And then Mr. Buehler, who is at
4	exhibit, Exhibit 7, which is "Approval Package	4	the FDA here, you had mentioned he moved from the
5	for: Application Number: 76-168, Generic Name:	5	FDA to Teva.
6	Oxycodone Hydrochloride Extended-release Tablets,	6	He was on that same org chart.
7	80 milligrams, Sponsor: TEVA Pharmaceuticals	7	Right? That org chart. Right?
8	USA, Approval Date: March 23, 2004."	8	A. Yes.
9	Now, this was an approval	9	Q. So this is it says, "This is
10	package. There's no Bates number. It's	10	in reference to your abbreviated new drug
11	something that we pulled off the FDA website.	11	application (ANDA) dated May 8, 2001, submitted
12	So that is where this comes from.	12	pursuant to Section 505(j) of the Federal Food,
13	But if we could take a look here.	13	Drug, and Cosmetic Act (the Act), for Oxycodone
14	Moving to the approval letter,	14	Hydrochloride Extended-release Tablets,
15	which is page 4, if you could go to that, it's	15	80 milligrams."
16	dated March 23, 2004. That's a stamped date at	16	Are you and you could maybe
17	the top. And it's a letter from Teva	17	take a look at Exhibit 2.
18	Pharmaceuticals or to Teva Pharmaceuticals,	18	Is this a product that Teva still
19	USA, attention Philip Erickson. And it's signed	19	sells or markets right now, or at least as of
20	by Gary Buehler, director, Office of Generic	20	2016, Teva's chart?
21	Drugs.	21	MS. HILLYER: Objection to the
22	So this, again, we talked about	22	extent it calls for speculation and lack
23	Mr. Erickson.	23	of foundation.
24	He was at the company in that org	24	THE WITNESS: Yeah. Even if I
	Davis 147		Davis 140
	Page 147		Page 148
1	looked at Exhibit 2, I don't know if it's	1	ANDA 76-168, oxycodone hydrochloride extended
2	currently being manufactured or not.	2	release tablets, 80 milligram.
3	Again, Teva has a vast portfolio of	3	You would agree with me that the
4	products, over 1,000, close to 1,300	4	approval is at least for some type of generic
5	approved applications, so I'm not sure	5	OxyContin. Right?
6	which ones are actively being marketed or	6 7	A. The approval is for generic
7	not.		OxyContin, 80 milligrams.
8	BY MR. CRAWFORD:	8	Q. Right. And then do you know if
9	Q. All right. Well, go to page 8.	9	it's one of these two referenced in this chart,
10	And you'll agree with me there does appear MS. HILLYER: Of exhibit?	10	the first one showing prescriptions starting in
11		11 12	2015 and then continuing into 2016, the second
12	MR. CRAWFORD: Of Exhibit 2, I'm		one just in 2016? A. I have no idea.
13	SOTTY.	13	
14	MS. HILLYER: Give him a second. BY MR. CRAWFORD:	14 15	Q. Okay. All right. Are you aware
15		16	that Teva, prior to this date, that Teva had a generic OxyContin approved?
16	Q. It's the chart of drugs. Page 8,	17	
17	the top two.	18	
	Vous agree with me that this shout		Q. Prior to today.
18	You agree with me that this chart		· · · · · · · · · · · · · · · · · · ·
18 19	says reflects, "Oxycodone Hydrochloride	19	A. Yes.
18 19 20	says reflects, "Oxycodone Hydrochloride Extended-Release tablets (Generic OxyContin)."	19 20	A. Yes.Q. And were you aware prior to
18 19 20 21	says reflects, "Oxycodone Hydrochloride Extended-Release tablets (Generic OxyContin)." The first two boxes state that.	19 20 21	A. Yes. Q. And were you aware prior to reviewing the chart yesterday that Teva had a
18 19 20 21 22	says reflects, "Oxycodone Hydrochloride Extended-Release tablets (Generic OxyContin)." The first two boxes state that. Correct?	19 20 21 22	A. Yes. Q. And were you aware prior to reviewing the chart yesterday that Teva had a generic OxyContin product?
18 19 20 21	says reflects, "Oxycodone Hydrochloride Extended-Release tablets (Generic OxyContin)." The first two boxes state that.	19 20 21	A. Yes. Q. And were you aware prior to reviewing the chart yesterday that Teva had a

	Page 149		Page 150
1	A. Yes.	1	Q. And then volume is above that.
2	Q. What is your understanding of	2	Scripts. And I assume that that type of number
3	when that product this shows an approval in	3	is being carried over. Certainly it isn't market
4	2004, Exhibit 7. Correct?	4	share. It looks to me like script volume but,
5	A. Yes.	5	you know, that's how I interpret it.
6	Q. And then Exhibit 2 has is	6	Do you interpret it that way?
7	referencing the sales of prescriptions in just	7	A. I'm not certain.
8	in 2015 and 2016 for those top two boxes. Right?	8	Q. So do you have any recollection
9	MS. HILLYER: Same objections.	9	of the generic OxyContin and whether that was
10	BY MR. CRAWFORD:	10	marketed prior to 2015?
11	Q. I'm looking at page 8.	11	A. Yeah, I mean, I am not certain.
12	A. Right. But I am looking at page	12	Again, we have over 1,300 approved products. And
13	2 to understand what the chart is. It says	13	I don't get involved in the details of every
14	"Script volume and share of Teva products	14	product.
15	relative to all opioids."	15	Q. I understand.
16	So again, I'm not certain. I	16	But I'm just wondering if you
17	didn't prepare these charts. I'm not I didn't	17	have any knowledge or recollection of what was
18	see them before yesterday, so I don't know what	18	happening with generic OxyContin and whether it
19	these numbers are, other than script volume, I	19	was being marketed or couldn't be marketed or
20	guess. I don't see where share is.	20	anything at all?
21	Q. Well, share would be in that	21	A. No, nothing that stands out in my
22	in the charts on 1 and 2. It says, "Teva CII	22	memory.
23	opioid share." And there's a percent.	23	Q. Sure. And that's all I want to
24	A. Okay.	24	get, is just your memory.
	Page 151		Page 152
1	A. Yeah. I'm not certain.	1	Q. But at least a generic product,
2	Q. If you don't, that's perfectly	2	you've heard of a court stopping the marketing.
3	okay.	3	Right?
4	A. Right.	4	A. Yes.
5	Q. So moving on with the letter,		
	-	5	Q. Even though it's FDA approved.
6	have you ever seen this approval letter before?	6	Right?
7	have you ever seen this approval letter before? A. This specific one, no, not that I	6 7	Right? A. Yes.
7 8	have you ever seen this approval letter before? A. This specific one, no, not that I recall.	6 7 8	Right? A. Yes. Q. And that might be because there's
7 8 9	have you ever seen this approval letter before? A. This specific one, no, not that I recall. Q. How about one for generic	6 7 8 9	Right? A. Yes. Q. And that might be because there's some kind of patent dispute or a dispute about
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7 8 9 10 11 12 13 14 15 16 17 18	have you ever seen this approval letter before? A. This specific one, no, not that I recall. Q. How about one for generic OxyContin, have you ever seen an approval letter for that? A. Not that I recall. Q. So it does say on the third paragraph, the application is approved. And so once an application is approved I guess unless there's a court injunction or something like that, Teva is free to market the product. Right? A. Yes. Q. Have you ever heard of a court	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Right? A. Yes. Q. And that might be because there's some kind of patent dispute or a dispute about whether Teva could legally market it and not infringe on the rights of a brand or another manufacturer? A. Yes. Q. So going to page 3 of the letter, the second paragraph there, starting with, "TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 milligram, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments)
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7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	have you ever seen this approval letter before? A. This specific one, no, not that I recall. Q. How about one for generic OxyContin, have you ever seen an approval letter for that? A. Not that I recall. Q. So it does say on the third paragraph, the application is approved. And so once an application is approved I guess unless there's a court injunction or something like that, Teva is free to market the product. Right? A. Yes. Q. Have you ever heard of a court injunction or something preventing Teva from marketing an FDA-approved generic opioid?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Right? A. Yes. Q. And that might be because there's some kind of patent dispute or a dispute about whether Teva could legally market it and not infringe on the rights of a brand or another manufacturer? A. Yes. Q. So going to page 3 of the letter, the second paragraph there, starting with, "TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 milligram, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that TEVA was
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	have you ever seen this approval letter before? A. This specific one, no, not that I recall. Q. How about one for generic OxyContin, have you ever seen an approval letter for that? A. Not that I recall. Q. So it does say on the third paragraph, the application is approved. And so once an application is approved I guess unless there's a court injunction or something like that, Teva is free to market the product. Right? A. Yes. Q. Have you ever heard of a court injunction or something preventing Teva from marketing an FDA-approved generic opioid? A. An opioid specifically, I'm not	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Right? A. Yes. Q. And that might be because there's some kind of patent dispute or a dispute about whether Teva could legally market it and not infringe on the rights of a brand or another manufacturer? A. Yes. Q. So going to page 3 of the letter, the second paragraph there, starting with, "TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 milligram, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that TEVA was the first ANDA applicant to submit a
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	have you ever seen this approval letter before? A. This specific one, no, not that I recall. Q. How about one for generic OxyContin, have you ever seen an approval letter for that? A. Not that I recall. Q. So it does say on the third paragraph, the application is approved. And so once an application is approved I guess unless there's a court injunction or something like that, Teva is free to market the product. Right? A. Yes. Q. Have you ever heard of a court injunction or something preventing Teva from marketing an FDA-approved generic opioid?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Right? A. Yes. Q. And that might be because there's some kind of patent dispute or a dispute about whether Teva could legally market it and not infringe on the rights of a brand or another manufacturer? A. Yes. Q. So going to page 3 of the letter, the second paragraph there, starting with, "TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 milligram, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that TEVA was

Page 153 Page 154 1 Hydrochloride Extended-release Tablets, 80 1 the brand would also sell an authorized generic, 2 milligram, containing paragraph IV certifications 2 but you could be on the market for a period of 3 to each patent listed in the "Orange Book." This 3 six months before any other generic applicants 4 exclusivity will begin to run from the date TEVA 4 can get approved. 5 begins commercial marketing of the drug product, 5 Q. And that's a competitive 6 or upon the decision of a court holding the 6 advantage in the generic world, to have the 7 patents which were the subjects of the paragraph 7 180-day exclusivity. Right? 8 IV certifications to be invalid or not infringed; 8 MS. HILLYER: Objection to form. 9 THE WITNESS: 180-day exclusivity whichever occurs first." 9 10 10 And then moving down, second is very important in the generics. 11 paragraph, the second line, "The Agency expects BY MR. CRAWFORD: 11 12 that you will begin commercial marketing of this 12 Q. And why is that? 13 drug product in a prompt manner." 13 A. Because it's an opportunity to be 14 So can you explain what this 14 on the market without any other generic 15 180-day generic drug exclusivity is that's been 15 competition, other than possibly an authorized 16 granted here? 16 generic by the brand. 17 A. Sure. So for generic applicants, 17 Q. An authorized generic meaning one 18 if you are the first generic applicant to file an 18 that the brand is allowing another manufacturer 19 ANDA, and if FDA receives that application 19 to make it but as a generic. Right? 20 wherein you are challenging patents that are 20 A. Not necessarily. So it's -- an 21 listed in the Orange Book, if you are able to 21 authorized generic is when the brand in essence 22 obtain approval, then you can potentially have a 22 packages its product and puts the label of 23 period of 180-day generic exclusivity where you, 23 another generic applicant on it. 24 as an ANDA applicant and the brand, and typically 24 So another generic company isn't Page 155 Page 156 manufacturing it. 1 That's because you would assume, 1 2 2 wouldn't you, that that then triggers the 180-day Q. Right. 3 The brand manufactures it and 3 period once you start marketing. Right? 4 uses the label for another generic company. 4 MS. HILLYER: Objection to form. 5 Q. Okay. So the authorized generic 5 THE WITNESS: Can you repeat your б is the company that it uses. б question, please? 7 7 BY MR. CRAWFORD: Is there a separate application 8 process to be an authorized generic --8 Yeah. 9 9 Is -- the FDA wants Teva to begin A. No. 10 Q. -- or can you just adopt the 10 marketing the drug promptly. 11 11 Is that because, in your view and brand one? 12 It's all managed under the brand 12 expertise in the area of regulatory affairs, that A. 13 NDA. 13 that's triggering the 180-day period. Right? 14 Q. Do you know if Teva -- is Teva an 14 MS. HILLYER: Objection to form. authorized generic for any generic drugs that you 15 THE WITNESS: My understanding is 15 16 know of? 16 that is because it would trigger the 17 A. Yes. 17 exclusivity period to start to run. BY MR. CRAWFORD: 18 So do you know if Teva is an 18 19 authorized generic for any opioid products? 19 Q. Right. The goal of this is to 20 20 incentivize drug companies to -- the exclusivity A. I'm not certain. 21 So with this exclusivity, it does 21 is to incentivize drug companies to challenge 22 22 say, "The Agency expects you will begin patents and get cheaper generics on the market, commercial marketing of this drug product in a 23 23 and in return the FDA or the regulations grant 24 prompt manner." 24 this exclusivity period for the successful

	Page 157		Page 158
1	manufacturer. Correct?	1	successfully manufacture the product and have the
2	A. So the goal of this is to bring	2	proper controls in place.
3	safe, affordable, high quality, lower cost	3	Q. Right. But any manufacturer can
4	generics to the market and increase competition	4	make that attempt at that point in time to get
5	in the marketplace.	5	approval, right, after the 180 days is up?
6	Q. By increase competition by	6	A. Yes.
7	bringing in a generic product where previously	7	Q. So then moving to the top of the
8	there has only been a brand?	8	last page. It says, "Post-marketing reporting
9	A. Right. But only if they	9	requirements for this abbreviated application are
10	challenge patents and are able to bring the	10	set forth in 21 CFR 314.80-81 and 314.98. The
11	product to market before those patents expire.	11	Office of Generic Drugs should be advised of any
12	Q. Right. Then after 180 days,	12	change in the marketing status of the drug."
13	presumably any company can issue a generic	13	So in your view, is Teva, when it
14	version of a drug after 180 days. Right?	14	gets an ANDA approval by the FDA, that it must
15	A. Not any company. You would have	15	adhere to the reporting requirements of Sections
16	to submit an application to the FDA and FDA would	16	314.80 to 81 and 314.98?
17	have to find it, you know, approvable.	17	MS. HILLYER: Objection to form.
18	Q. Right. Approvable meaning it's	18	THE WITNESS: Yes. So yes. I'm
19	bioequivalent. Right?	19	not certain what is specifically stated
20	A. Correct.	20	in these sections of the CFR without
21	Q. And the same label, too?	21	looking at them, but yes, this is what I
22	A. But it's not only bioequivalent,	22	spoke to earlier about ensuring
23	but yes. It has to have the same label. It has	23	compliance and filing annual reports, as
24	to be you have to show that you can	24	well as the pharmacovigilance team filing
24	to be you have to show that you can		1 5
	Page 159		Page 160
1	adverse event reports and what have you.	1	BY MR. CRAWFORD:
2	BY MR. CRAWFORD:	2	Q. So while we're marking this,
3	Q. Right. And that's what 80 and 81	3	we've marked Exhibit 8, 9 and 10, which are the
4	do, one is dealing with pharmacovigilance	4	three sections mentioned. And Section 8 is
5	reporting and the other is annual reporting.	5	314.80. Exhibit 9 is 3 314.81.
6	Right?	6	These are kind of dense, but, I
7	A. I'm not certain.	7	mean, you're head of regulatory, you're familiar
8	MS. HILLYER: Objection to form.	8	with these provisions generally. Right?
9	THE WITNESS: I'm sorry.	9	A. Yes.
10	BY MR. CRAWFORD:	10	Q. And 314.80, correct me if I'm
11	Q. I've got them here. Let's mark	11	wrong, concerns you'll agree with me, it
12	them and just confirm them.	12	concerns reporting adverse events, say 15-day
13		13	reports, and then quarterly and eventually annual
14	(Deposition Exhibit No.	14	reports on adverse events. Right?
15	Teva-Tomsky-8, Code of Federal	15	MS. HILLYER: Hold on one second.
16	Regulations Title 21, Section 314.80, 6	16	I have my 8 and 10 are the
17	pages; Deposition Exhibit No.	17	same.
18	Teva-Tomsky-9, Code of Federal	18	Are yours different?
19	Regulations Title 21, Section 314.81, 8	19	THE WITNESS: No, they're
20	pages; and Deposition Exhibit No.	20	different.
21	Teva-Tomsky-10, Code of Federal	21	MS. HILLYER: So my 8 is section
22	Regulations Title 21, Section 314.98, 4	22	80.
23	pages, were marked for identification.)	23	MR. CRAWFORD: Right. That's
	· - /		E Company
24		24	correct.

	Page 161		Page 162
	_		
1	MS. HILLYER: 9 is 81.	1	You tell me, but I think you have
2	MR. CRAWFORD: That's correct.	2	two copies right there.
3	MS. HILLYER: I must have I	3	MR. CRAWFORD: Oh. That would
4	just have a duplicate.	4	explain it.
5	THE WITNESS: You don't have a	5	THE WITNESS: I have two copies,
6	10.	6	too.
7	MS. HILLYER: I don't have a 10.	7	MS. HILLYER: The actual exhibit
8	MR. CRAWFORD: Do you have 10?	8	is two copies, too, so do you want
9	MS. HILLYER: No.	9	just for the record.
10	THE WITNESS: No.	10	MR. CRAWFORD: Okay.
11	MR. JENSEN: So you're missing	11	MS. HILLYER: Thank you. You
12	98?	12	gave me yours.
13	MS. HILLYER: Yes.	14	Do you care?
14	MR. CRAWFORD: We'll throw it up		MR. CRAWFORD: No, I don't. BY MR. CRAWFORD:
15	on the board and blow it up. And you can	15	
16 17	have my copy. MS. HILL VED: This is yours?	16 17	Q. So and then 314.81 is a
18	MS. HILLYER: This is yours? MR. CRAWFORD: Yes.	18	different type of report that has to be submitted.
19	BY MR. CRAWFORD: Yes.	19	
20		20	That's the annual report. Right? A. 314.81 talks about NDA field
21	Q. So Exhibit 8, 314.80, dealing	21	
22	with periodic reporting and 15-day reports of adverse events. Correct?	22	alert reports, as well as annual reports.
23		23	Q. All right. So down at the bottom
24	MS. HILLYER: Is it just a two-pager?	24	of the first page, annual reports, so it's your understanding that that's separate from the
24	two-pager:	24	understanding that that's separate from the
	Page 163		Page 164
	<u> </u>		Page 104
1		1	
1 2	reports that are submitted with regard to 314.80.	1 2	A. So I can tell you, not
			A. So I can tell you, not necessarily.
2	reports that are submitted with regard to 314.80. Right? A. Yes.	2	A. So I can tell you, not
2	reports that are submitted with regard to 314.80. Right? A. Yes.	2 3	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi),
2 3 4	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in	2 3 4	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v)
2 3 4 5	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice	2 3 4 5	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information
2 3 4 5 6	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual	2 3 4 5 6	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report.
2 3 4 5 6 7	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81?	2 3 4 5 6 7	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on
2 3 4 5 6 7 8	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes.	2 3 4 5 6 7 8	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right?
2 3 4 5 6 7 8	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a	2 3 4 5 6 7 8 9	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes.
2 3 4 5 6 7 8 9	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are	2 3 4 5 6 7 8 9	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not
2 3 4 5 6 7 8 9 10	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right?	2 3 4 5 6 7 8 9 10 11	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual
2 3 4 5 6 7 8 9 10 11	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10.	2 3 4 5 6 7 8 9 10 11	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right?
2 3 4 5 6 7 8 9 10 11 12 13	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep.
2 3 4 5 6 7 8 9 10 11 12 13 14	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at	2 3 4 5 6 7 8 9 10 11 12 13 14	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi).
2 3 4 5 6 7 8 9 10 11 12 13 14 15	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any
2 3 4 5 6 7 8 9 10 11 12 13 14 15	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section. Right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right? A. Distribution data, summary,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section. Right? A. Which section?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right? A. Distribution data, summary, labeling. Distribution talks about authorized
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section. Right? A. Which section? Q. 314.81.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right? A. Distribution data, summary, labeling. Distribution talks about authorized generics, so I guess there could be a case where
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section. Right? A. Which section? Q. 314.81. A. But which section?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right? A. Distribution data, summary, labeling. Distribution talks about authorized generics, so I guess there could be a case where a generic is allowing another manufacturer to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	reports that are submitted with regard to 314.80. Right? A. Yes. Q. And does Teva, is it its practice to submit both the periodic and 15-day reports in 314.80, and also submit separately the annual reports called for in 314.81? A. Yes. Q. And then 314.98 I think is a provision that indicates both .80 and .81 are applicable to ANDA holders or generics. Right? And we're looking at Exhibit 10. A. Yes. Q. All right. So let's look at Exhibit 9, which is the annual reports. And this is applicable to both generic and brand manufacturers, this section. Right? A. Which section? Q. 314.81. A. But which section? Q. Well, the entire section.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. So I can tell you, not necessarily. So if you look in 314.81(2)(vi), for example, it talks about clinical data and (v) talks about nonclinical data. That information isn't submitted in an ANDA annual report. Q. All right. So that's starting on page 3, about three paragraphs down. Right? A. Yes. Q. So that's something that is not generally submitted within a generic annual report. Right? A. Correct. And even yes, yep. Those two, (v) and (vi). Q. But above that, are there any the provisions above that are applicable to generics and brands. Right? A. Distribution data, summary, labeling. Distribution talks about authorized generics, so I guess there could be a case where a generic is allowing another manufacturer to distribute a generic under their label.

Page 165 Page 166 1 Q. Okay. So you're saying (ii)(b) 1 Is there -- they might have an 2 2 might not apply to all generics. It certainly ANDA for the same drug, just simply be an 3 3 doesn't apply to a brand. It's just a section authorized generic because the brand is making it 4 applicable to an authorized generic. Right? 4 for that generic company? 5 A. Well, it would -- it would apply 5 A. I'm not sure I understand what 6 to a brand. 6 you just said. 7 7 Q. Okay. Q. All right. I'm just -- you were 8 8 And I guess some generics may talking about another generic manufacturer under 9 choose to distribute or allow another company to 9 an ANDA that's for an authorized generic. I distribute under their ANDA. I'm sure it 10 10 didn't understand that. 11 happens. 11 So we spoke about an authorized Q. So when you have -- when you have 12 12 generic as it relates to an NDA, how they would 13 an authorized generic, do you have to have an 13 maybe supply the product to a generic company and 14 ANDA number for the authorized generic drug that 14 a generic company would give the brand company 15 you distribute, or do you just go under the NDA 15 its label to put on the NDA product. So it would 16 number of the brand? 16 be sold as an authorized generic. Correct? 17 So if you have an authorized 17 Q. Right. 18 generic that's being distributed under an NDA, it 18 So then there's another case that A. 19 would all be associated with that NDA number. 19 I can foresee where an ANDA holder --20 But I'm saying I can foresee an example of when 20 Of what? 21 an ANDA applicant also may choose, for some other 21 Α. I'm sorry? An ANDA holder of what? 22 reason, to allow another manufacturer to 22 O. 23 distribute under the ANDA an authorized generic. 23 Of any product. A. 24 So I'm trying to understand. 24 Q. Okay. Page 167 Page 168 A. Say -- I don't know, say Administration at the specified time two copies 1 1 2 ibuprofen, for example. Say I, Scott Tomsky, 2 of the following reports." 3 have an ANDA for ibuprofen. I may choose to say, 3 And skipping down to the bottom 4 hey, here you go. If you want to put your label 4 of page 1 to 2, "Annual report." It says, "The 5 and distribute product under my ANDA, so that 5 applicant shall submit each year within 60 days 6 could technically be an authorized generic as 6 of the anniversary date of U.S. approval" --7 well. 7 again, that was the 60 days you referenced 8 So a generic authorizing another 8 earlier. Right? 9 generic company to make its product under its 9 A. That's correct. 10 ANDA? 10 -- "of the application, two 11 A. So again, that other company 11 copies of the report to the FDA division 12 wouldn't make the product, it would just simply 12 responsible for reviewing the application. Each 13 put its label on the product that's being made 13 annual report is required to be accompanied by a 14 under the ANDA. 14 completed transmittal Form FDA 2252 (Transmittal 15 15 of Periodic Reports for Drugs for Human Use), and O. Got it. 16 Okay. Going back to 314.81, 16 must include all the" relevant "information" --17 "Applicability." 17 "all the information required under this section that the applicant received or otherwise obtained 18 It says, "Each applicant shall 18 19 make the reports for each of its approved 19 during the annual reporting interval that ends on 20 applications and abbreviated applications 20 the U.S. anniversary date. The report is 21 required under this section and Section 505(k) of 21 required to contain in the order listed," colon. 22 the act." 22 So the first item is "Summary." 23 (b) is "Reporting requirements. 23 And it's required to provide "A brief summary of 24 The applicant shall submit to the Food and Drug 24 significant new information from the previous

Page 169 Page 170 1 year that might affect the safety, effectiveness, 1 Q. What if the ANDA holder becomes 2 2 or labeling of the drug product. The report is" aware that its generic drugs are being abused or 3 require -- "also required to contain a brief 3 misused, say in the case of an opioid, during 4 description of actions the applicant has taken or 4 that one-year period, and that maybe the label 5 intends to take as a result of this new 5 isn't -- and the doctors aren't properly 6 information." 6 prescribing the drug. 7 So are your annual reports as, 7 Is that something that you feel 8 8 again, a business practice, do they contain this Teva would be required to put into its annual 9 9 summary that's just described in subdivision (i)? report? 10 10 MS. HILLYER: Objection to form. A. So an ANDA annual report will 11 contain a summary of new information related to: 11 THE WITNESS: Can you break down 12 If there was any changes to the approved 12 your question for me, please? 13 specification, if there was changes to any of the 13 BY MR. CRAWFORD: Q. Okay. So let's say Teva became 14 14 manufacturing batch records, if there was a 15 supplement that was filed maybe to add another 15 aware during that annual period that, say, its 16 API source that we talked about. Anything like 16 generic OxyContin was being misprescribed and 17 that. 17 abused and misused by patients to become addicted 18 18 So it would contain a summary, or -- would -- and they became aware of that 19 but not necessary a summary of safety 19 information during that period. 20 information, which is stated here. 20 Is that something that you feel 21 Q. Why wouldn't it contain that? 21 that Teva would be required to report in its 22 Because ANDAs aren't required to 22 annual report? 23 generate safety or efficacy data. That's only a 23 MS. HILLYER: Objection to form. 24 THE WITNESS: So I can say from 24 requirement of NDAs. Page 171 Page 172 1 an ANDA perspective, generic applicants 1 and manufacturing changes for a product. 2 primarily in their annual reports provide 2 Q. But isn't the purpose of this 3 a summary of the chemistry, manufacturing 3 section to alert the FDA that there's a problem 4 and control changes, which is what I 4 with the safety of the drug or how it's being 5 described earlier, any changes that are 5 prescribed so they could potentially or with the 6 made during the reporting period as it 6 manufacturer take corrective action? 7 relates to anything that's already 7 MS. HILLYER: Objection to form. 8 approved in the application. 8 THE WITNESS: No, that has not 9 The scenario that you described I 9 been my experience. 10 would think would be something that would 10 BY MR. CRAWFORD: 11 be included in the other type of 11 Q. And it does say that the report 12 reporting that we looked at in 314.80, 12 is also required to contain a brief description possibly. But it's nothing that would be 13 13 of actions the applicant has taken or intends to submitted in a drug product annual report 14 14 take as a result of this new information. 15 like this for an ANDA. 15 So wouldn't you agree with me 16 BY MR. CRAWFORD: 16 that if, say, for the generic OxyContin, if that 17 But wouldn't knowledge about 17 was marketed prior to a REMS approval, and the 18 abuse of its drug and misuse be information that 18 company became aware that a drug was being 19 might affect the safety of the generic product? 19 misused or abused or misprescribed, say in the

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A. Again, I'm not certain. Again,

regulatory affairs and ANDAs, the information

report pertains to the summary of the chemistry

that's required to be submitted in an ANDA annual

what I'm saying is, in my years of doing

MS. HILLYER: Objection to form.

THE WITNESS: So no, again, what

case of an opioid drug, wouldn't, one, Teva be

required to report that in an annual report and

also report corrective steps it was taking?

Page 173 Page 174 1 I'm saying is that in my experience, in 1 I'm sorry, it's 314.81(B)(1), NDA my communications with FDA, is the 2 2 field alert. 3 And so what page is this on? 3 expectation that an ANDA applicant in its O. 4 annual report file changes related to the 4 A. It's on the first page. 5 5 So basically the field alert chemistry and manufacturing controls. 6 report would be information concerning any 6 And what that previous section was 7 talking about what would be what's 7 incident that causes the drug or its labeling to 8 8 covered in Section 314.81(b)(1), which be mistaken for or applied to another article. 9 talks about NDA field alerts, ANDA field 9 So that's like a mistaken use of 10 the drug, they think it's some other drug or 10 11 something? 11 So if you receive a product complaint with respect to maybe a product 12 12 A. So -- correct. It could be that not working or somebody didn't have 13 somehow the wrong label was put on the product or 13 14 enough tablets in their bottle or maybe 14 there was an error in the label that was on the 15 the wrong imprint code was found in a 15 product. So those are the type of events that 16 16 bottle, that's when it would trigger an would have to be reported to FDA in a field 17 NDA field alert to be filed, and those 17 letter and then summarized again in the annual 18 are the types of summary and information 18 report. 19 that would be included in this annual 19 Q. And then the second thing is, 20 "Information concerning any bacteriological 20 report. 21 BY MR. CRAWFORD: 21 contamination, or any significant chemical, 22 22 physical, or other change or deterioration in the And what section is that here? 23 Can you point that out? You've mentioned it, 23 distributed drug product, or any failure of one 24 but it's --24 or more distributed batches of the drug product Page 175 Page 176 1 cover the situation I'm talking about, you'd to meet the specification established for it in 1 2 2 agree, about Teva becoming knowledgeable that its the application." 3 3 drug is being abused or misused or misprescribed So that's concerning really 4 contamination or a defective batch of product. 4 that's leading to addiction or some kind of 5 Right? 5 safety issue like that. Right? 6 A. Right. So that's talking about 6 MS. HILLYER: Objection to form. 7 if a patient receives a product and they look at 7 THE WITNESS: Again, the scenario 8 it and it turned brown and it's supposed to be 8 you described is not covered in ANDA 9 white. Or if the manufacturing company had -- it 9 annual reports. 10 runs routine stability reports. So if it ran a 10 BY MR. CRAWFORD: 11 report and it received a result that was outside 11 Q. But it does say, you agree with 12 of the approved specification. Those, again, are 12 me, the summary is supposed to provide a summary 13 instances that would trigger a field alert and 13 of significant new information from the previous 14 that type of information would be summarized in 14 year that might affect the safety, effectiveness 15 or labeling of the drug product. Right? 15 this section. 16 Q. Right. And that has to be done 16 Are generic companies exempt from 17 within three days. Right? 17 that in any way? 18 A. So the field alert needs to be 18 MS. HILLYER: Objection to form. 19 filed within three days. But then the annual 19 THE WITNESS: So what I'm 20 20 saying -- so what I'm saying is yes, this report would capture a summary of any field 21 alerts that were filed within that one-year 21 section of the regulation is for both 22 reporting period that the annual report is 22 NDAs and ANDAs. And there are different 23 covering. 23 responsibilities for NDA applicants 24 Q. Right. But that doesn't really 24 versus ANDA applicants. And in my

Page 177 Page 178 1 experience in working with FDA and in the 1 manufacturers don't have to report the type of 2 2 industry for over 20 years, there's never safety information example I gave to you on abuse 3 3 been a requirement in ANDA annual and misuse? 4 reports, and nor is it FDA's expectations 4 I'm not aware of anything 5 that any safety or efficacy information 5 written. I know I've specifically had 6 is reported in an ANDA annual report. 6 conversations with FDA about this when I was at 7 That is left to the NDA holder. 7 Ranbaxy. 8 8 BY MR. CRAWFORD: Ranbaxy. O. 9 9 What about a name brand drug, if How about at Teva? 10 they become aware of a safety issue with regard 10 No. to abuse or misuse in the prior year, would they And who is the person at the FDA 11 11 Q. 12 be expected, in your view as a regulatory person 12 you had the conversation with? 13 with regulatory experience, to report that in 13 His name was Peter Rickman. And what was his position? 14 their annual report? 14 15 MS. HILLYER: Objection to form, 15 A. He was a director in the Office 16 calls for speculation, to the extent it's 16 of Generic Drugs. 17 outside of his purview. 17 And is there anything in writing? THE WITNESS: Yeah. Again, I am Did he confirm this in email or did you confirm 18 18 19 not certain. I've worked in the generic 19 it in any kind of report with Ranbaxy? 20 industry for 99 percent of my career. 20 Not that I recall. 21 BY MR. CRAWFORD: 21 Q. What was the context of when it 22 Q. All right. So where -- is there 22 was raised? 23 a written guidance or -- from the FDA or anything 23 A. It was, again, confirming what information had to be filed in an annual report. 24 in writing that you can point to that generic 24 Page 179 Page 180 1 1 at the FDA that you didn't have to put this I don't know how it came up. There was some 2 discussion that was going on within the company 2 information in an ANDA? 3 about what needed to be filed in an ANDA versus 3 No. I spoke with him. 4 Just Mr. Rickman? 4 an NDA annual report. And, clearly, the clinical O. 5 5 and safety information. A. Correct. 6 6 How many occasions did he tell Q. But he said you don't have to O. 7 report any safety information other than the 7 you this? 8 clinical and safety information? 8 A. It was one conversation that I 9 MS. HILLYER: Objection to form. 9 had with him. 10 BY MR. CRAWFORD: 10 Okay. And was it -- was there a 11 Q. I'm just trying to understand. 11 specific safety issue that you ran by him about 12 whether you had to put it in or not? 12 What did he tell you, you didn't have to report that or just simply told you that 13 13 you had to report the clinical information? It was just a general question? 14 14 Q. 15 He said that the safety and 15 Correct. efficacy information is not applicable to an 16 All right. The next section, 16 17 ANDA. 17 (ii)(a), "Distribution data," it says, 18 "Information about the quantity of the drug 18 Did he give a reason for that? Q. 19 A. No. It's been a long-standing 19 product distributed under the approved 20 20 position from the agency. application, including that distributed to 21 But it's never been put in 21 distributors. The information is required to 22 include the National Drug Code (NDC) number, the 22 writing, as far as you're aware? 23 A. Not that I'm aware of. 23 total number of dosage units of each strength or 24 Did you hear it from anyone else 24 potency distributed (e.g., 100,000 over

Page 181 Page 182 5 milligram tablets, 50,000 over 10 milliliter So I believe it's Jill Pastore 1 1 2 vials), and the quantities distributed for 2 would still collect that data and then save it on 3 domestic use and the quantities distributed for 3 the shared drive and make it available to the 4 foreign use. Disclosure of financial or pricing 4 team in India. 5 data is not required." 5 Q. And then these annual reports, if 6 Is that something that Teva, 6 you wanted to get a copy of an annual report, can 7 through its normal business practices, includes 7 you personally go on the shared drive and pull it 8 in its annual reports for its ANDAs? 8 up, or how do you get them for a drug? 9 A. Yes. Distribution data. 9 A. Yes, yes. 10 10 Q. Do you just look up the drug and Q. And who currently at Teva is 11 responsible for collecting this information and there's a folder or a search pulls them up or 11 12 putting it in the annual reports? 12 something? 13 A. So the regulatory team would 13 A. Yes. I would search by the name 14 collect that from the supply chain and commercial 14 of a product or an ANDA number. 15 marketing team. 15 Q. I would love to have an example, 16 The regulatory team being the one 16 but we have trouble finding them in the document 17 putting the annual report together? 17 production, so I don't have an example to show A. Yes. But it -- it's collected --18 you, so we'll talk about it. Either I can't find 18 19 I believe it's collected in the US, and then that 19 them or they're not there, so --20 20 MS. HILLYER: I think we offered information is given to the team in India. 21 Q. And where in the US is it 21 to give you samples and told you to 22 collected from? What department? I mean, from 22 follow up with us on which ones you 23 all the charts we went through, does that -- do 23 wanted samples of, and then you never 24 you remember where that responsibility lies? 24 did. Page 183 Page 184 MR. CRAWFORD: Well, I definitely So if you were an authorized 1 1 2 2 generic, if Teva was, and -- from some brand, my want them. 3 3 understanding of what an authorized generic is, So, but let's --4 MS. HILLYER: I think we're a 4 is that brand is making the drug and it's being 5 little past that timeline. 5 distributed by the generic under their name. MR. CRAWFORD: Got it. 6 6 Right? 7 MS. HILLYER: But we can talk 7 A. Yes. 8 about that offline. 8 Does that generic have to file an 9 MR. CRAWFORD: Understood. 9 annual report for that? 10 BY MR. CRAWFORD: 10 No. A. 11 Q. Okay. So the next section is 11 That's filed by the brand? O. 12 "Authorized generic drugs." We kind of went 12 through that. It says, "If applicable, the date 13 13 And then this section would be each authorized generic drug (as defined in... filled out by the brand? 14 14 15 314.3) entered the market, the date each 15 Correct. 16 authorized generic drug ceased being distributed, 16 All right. And then third is, 17 and the corresponding trade or brand name." 17 "Labeling. Currently used professional labeling, 18 So that's a section that you patient brochures or package inserts (if any), 18 19 would fill out only if you were an authorized 19 and a representative sample of the package 20 drug. Right? 20 labels." 21 A. Only if you were distributing an 21 That is also included in these 22 22 authorized generic under that application. annual reports as a practice. Right? 23 Q. Right. So -- so this -- so 23 A. Yes. basically, I'm just trying to understand. 24 24 Q. All right. That's all I have on

	Page 185		Page 186
1	those, but let's go back to Exhibit 7, which is	1	Q. And then there's other labeling,
2	the approval package for the generic OxyContin.	2	too. It's not necessarily a term of art,
3	Let's go to the label, which is a	3	approved label.
4	couple of pages afterwards, under "Final printed	4	It could be considered labeling,
5	labeling."	5	an advertisement or a "Dear Doctor" letter or
6	So is this the label that was	6	something. Right?
7	approved for Teva in this package for this	7	MS. HILLYER: Objection to form.
8	generic OxyContin.	8	THE WITNESS: It's possible.
9	In your professional career of	9	BY MR. CRAWFORD:
10	seeing these approvals, is this generally how it	10	Q. Do you refer to those as approved
11	comes back to you?	11	labels?
12	A. Yes, it appears to be.	12	A. I'm not sure I understand your
13		13	question.
		14	Q. Do you refer to an advertisement
14	taking a look at the last page of the label, it	15	as an approved label?
15	says, "Manufactured by Teva Pharmaceuticals USA."	16	A. No. An advertisement would be
16	So this would be Teva's label	17	
17	dated June of '03. Right?	18	based on the approved labeling. Q. But it's still considered
18	A. Yes.	19	*
19	Q. All right. And then again, to be		labeling, because it has information about the
20	a generic drug, you're this is called when	20	drug.
21	it's approved, it's called the approved label.	21	MS. HILLYER: Objection to form.
22	Right? Is that kind of a term of art, approved	22	BY MR. CRAWFORD:
23	label?	23	Q. Technically. Correct?
24	A. Yes.	24	A. Generally speaking, it would be
	Page 187		Page 188
1	accompanied by the approved label as well.	1	MS. HILLYER: Same objection.
2	Q. Is a "Dear Doctor" letter, is	2	THE WITNESS: I'm not certain.
3	that considered technically labeling?	3	BY MR. CRAWFORD:
4	MS. HILLYER: Objection to form.	4	Q. Can a generic drug company
5	THE WITNESS: I don't know. I	5	communicate information to doctors about its
6	mean "Dear Doctor" letters aren't used on	6	generic drugs consistent with its approved label?
7	the generic side, typically. It's only	7	MS. HILLYER: Objection to form.
8	something that would be used on a branded	8	THE WITNESS: Can you repeat your
9	side.	9	question again? Sorry.
10	BY MR. CRAWFORD:	10	BY MR. CRAWFORD:
11	Q. Can a generic manufacturer send	11	Q. Can a generic drug company
12	out a "Dear Doctor" letter about a drug, in your	12	communicate information to doctors about its
13	view?	13	generic drugs consistent with its approved label?
14	MS. HILLYER: Objection.	14	A. I think so, but I don't know any
15	Objection to form, calls for a legal	15	generic companies that have a sales team for
16	conclusion.	16	generics.
17	THE WITNESS: Yeah. I'm not	17	Q. Do they have safety teams,
18	certain. I don't think it's ever been	18	generic drug companies?
19	done that I'm aware of.	19	MS. HILLYER: Objection to form,
20	BY MR. CRAWFORD:	20	calls for speculation.
21	Q. Do you know if there's any	21	THE WITNESS: Yeah. I'm not sure
22	regulatory restriction precluding a generic drug	22	what you mean by that.
23	manufacturer from sending out a "Dear Doctor"	23	BY MR. CRAWFORD:
24	letter?	24	Q. Well, anyone in charge of safety,
-	101101.	-	Z on, anyone in charge of surery,

	Page 189		Page 190
1	if there's a safety issue or a danger that comes	1	evaluation and mitigation strategy.
2	out, is there any kind of dedicated person	2	That's the whole goal, is to make sure
3	designed or that's that exists within Teva,	3	that there's proper balance of the
4	their generic side, to	4	benefit/risk ratio and that the doctors
5	A. I think what you're describing	5	who are prescribing the products know how
6	is	6	to prescribe them and the patients that
7	Q address those issues?	7	are using them know how to use them and
8	A. Sorry. I think what you're	8	so forth.
9	describing is something that would be managed by	9	BY MR. CRAWFORD:
10	the pharmacovigilance team.	10	Q. Right. So that's one of the
11	Q. What if the company became aware	11	objectives of a REMS program. Right?
12	that its drug, its generic opioid products were	12	A. Correct.
13	being abused or misused by doctors, and the	13	Q. Is for doctors to know how to
14	doctors did not appear to understand the proper	14	properly use the drugs and what the risks are.
15	use of the drug or the safety risks with regard	15	Right?
16	to abuse and addiction, is it your view under the	16	A. Correct.
17	regulations that Teva could send a "Dear Doctor"	17	Q. But before, for some of these
18	letter or other information consistent with the	18	drugs, when this generic OxyContin was approved,
19	label to remind doctors how to properly use the	19	for instance, there was no REMS program for it.
20	drugs and about its risks?	20	Correct?
21	MS. HILLYER: Objection to form.	21	A. I'm not certain.
22	THE WITNESS: Yeah. Again, I'm	22	MS. HILLYER: Objection to form.
23	not certain, especially for this class of	23	THE WITNESS: Yeah. I'm not
24	drugs, which already has a approved risk	24	
24	drugs, which already has a approved risk	24	certain. The timeline's really meshed
	Page 191		
	rage 191		Page 192
1	together for me.	1	Page 192 Q. And those apply to all generics
1 2		1 2	
	together for me. BY MR. CRAWFORD:		Q. And those apply to all generics
2	together for me. BY MR. CRAWFORD:	2	Q. And those apply to all generics in those categories. Right?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	together for me. BY MR. CRAWFORD: Q. Well, REMS only came into effect in 2007 when the FDA could require. Right? A. Well, single shared REMS became effective in 2007. I'm not certain if there was other REMS that were in effect prior to that. Q. Right. I think under subpart H, the FDA could require a risk management plan, which is kind of a precursor, but only as part of the approval process. Right? A. For a brand product. Correct. Q. Well, for generic products, too. Right? A. Yeah. Again, that's something I'm not very familiar with. Q. REMS can apply and do apply to generics. Right? A. Yes. Q. And in fact, the current REMS in place for the transmucosal opioid products and the extended release and the immediate release	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And those apply to all generics in those categories. Right? A. Yes. Q. So my question is, is prior to these REMS programs, which are mandatory. Right? A. Right. Q. And each company submits its own REMS consistent with what the FDA wants for the class. Right? A. So each company has to submit the approved REMS the FDA approved REMS to its application. Yes. Q. That has to get approved as being in conformity with what they want. Right? A. Yes. Q. So before REMS were required, the immediate release, for instance, didn't have a REMS until 2018. Right? A. I'm not MS. HILLYER: Objection to form, calls for speculation. THE WITNESS: Yeah. I'm not

Page 194 Page 193 1 O. But recently. Right? 1 So before REMS was issued, and 2 2 A. I'm not certain on the timelines. before a drug was subject to it, could a generic 3 3 drug company like Teva communicate with doctors O. So before the approval of -about safety information concerning its products, 4 Teva's got immediate release opioid products they 4 5 sell. Right? 5 as long as it's consistent with its approved 6 A. I believe so. 6 label? 7 Q. Okay. So before the approval of 7 MS. HILLYER: Objection to form 8 the REMS, and my question is, is could Teva, is 8 on multiple levels, and assumes facts not 9 9 there anything in the regulations that would have in evidence is one of them. THE WITNESS: That's just not the 10 prohibited Teva from communicating with doctors 10 11 typical practice. I mean, a generic if they became aware that doctors may not have 11 12 12 company doesn't communicate with been aware of the risks of opioid products or 13 they were using Teva products or -- or proper 13 physicians. A generic company makes 14 use, that Teva could communicate with doctors 14 available the products based on an NDA 15 consistent with its label, safety and use 15 and a brand product. 16 information? 16 So the generic companies 17 MS. HILLYER: Objection to form. 17 aren't -- don't have salespeople. 18 THE WITNESS: If you could break 18 They're not going out and talking to 19 that down for me. 19 doctors. They're writing -- I mean, 20 BY MR. CRAWFORD: 20 they're manufacturing products. And in 21 Q. Okay. So you mentioned REMS. 21 some cases, physicians will prescribe a 22 I'm trying to find out like before the REMS. 22 brand, but if there's a generic 23 Immediate release had the REMS 23 available, it gets substituted either by 24 program in 2018, I'll represent. 24 an insurance company or a pharmacy. So Page 195 Page 196 1 generic companies don't go out and speak 1 mean, isn't the manufacturer primarily 2 2 to doctors. responsible for the safety of its product? 3 BY MR. CRAWFORD: 3 MS. HILLYER: Objection to form. 4 4 BY MR. CRAWFORD: Q. So -- but if a generic company 5 becomes aware that its products are being 5 Q. Or is it the FDA that's primarily 6 misprescribed or misused, who is going to tell б responsible for the safety of generic products? 7 7 the doctor? Whose responsibility is it then if Sorry, can you repeat your 8 it's not the generic company's? 8 question? 9 MS. HILLYER: Objection to form. 9 Who's responsible for the safety Q. THE WITNESS: I'm not certain 10 of generic products? Is it the generic 10 11 what you're asking. I mean, I think the 11 manufacturer that makes them or is it the FDA? 12 FDA has oversight over the, you know, the 12 Or is it the brand? 13 drugs that are approved in the United 13 MS. HILLYER: Objection to form. 14 States and they have postmarketing 14 THE WITNESS: I mean, FDA is 15 responsibility -- I mean, they put 15 responsible for approving safe and 16 postmarketing responsibility on the brand 16 effective generic drugs. And 17 companies, and FDA is aware of the same 17 manufacturers are responsible for 18 information. So generic companies would 18 manufacturing safe and effective generic 19 rely on the FDA to make such decisions, 19 drugs. 20 20 if there is additional steps which are BY MR. CRAWFORD: 21 required. In this case, assuming that's 21 Q. Right. So -- but what if, after 22 why the REMS were put in place. 22 it's approved by the FDA, it turns out that the 23 BY MR. CRAWFORD: 23 doctors aren't using the drugs, the generic drugs 24 What if the FDA doesn't know? I 24 safely, they're overprescribing it or they don't

	Page 197		Page 198
1	understand the safety risks.	1	misuse of opioids. But I think if opioids are
2	Who's responsible for	2	prescribed properly by physicians and used
3	communicating with the doctors, in your view, the	3	properly by patients and, you know, prescriptions
4	proper use and safety of the drug?	4	are filled by a licensed pharmacist, then they
5	MS. HILLYER: Objection to form.	5	are safe and effective as long as they're used
6	THE WITNESS: Each generic	6	according to the approved label that FDA has
7	company is going to have the same	7	approved.
8	information available to them that the	8	Q. And at what point did you
9	FDA would have available to them. FDA	9	personally become aware that they weren't being
10	would have the ability to see what's	10	properly used?
11	happening. And FDA would be the one to	11	MS. HILLYER: Objection to form.
12	make such decisions, which again, in this	12	THE WITNESS: I don't have any
13	case, I believe they did in putting a	13	personal recollection of when.
14	risk evaluation and mitigation strategy	14	BY MR. CRAWFORD:
15	in place.	15	Q. What if the company became aware
16	BY MR. CRAWFORD:	16	they were being improperly used before the FDA
17	Q. Do you believe there's an opioid	17	learned it? Who's responsible for telling the
18	epidemic right now?	18	FDA, one, and then who's responsible for trying
19	A. I'm not sure I have an opinion on	19	to correct it at that point in time?
20	it.	20	MS. HILLYER: Objection to form.
21	Q. There's certainly an opioid	21	THE WITNESS: Can you repeat your
22	some kind of opioid crisis going on.	22	question, please?
23	You understand that. Right?	23	BY MR. CRAWFORD:
24	A. I think there's an issue with	24	Q. Yeah.
			Q. 23
	Page 199		Page 200
1	So if the company learns about an	1	company become aware that there was
2	abuse or misuse problem with its opioids, a	2	misuse and abuse with its product?
3	generic drug company, who's responsible and	3	BY MR. CRAWFORD:
4	the FDA doesn't know about it yet, who's	4	Q. Didn't the company try to develop
5	responsible for alerting the FDA? First of all,	5	or want to develop an abuse-deterrent opioid?
6	let's break it down.	6	You were involved in that. Right?
7	Shouldn't the generic company	7	MS. HILLYER: Objection to form.
8	alert the FDA in its annual report on that safety	8	THE WITNESS: I wasn't involved
9	issue, whether it knows it or not?	9	in the development of abuse-deterrent
10	MS. HILLYER: Objection to form.	10	opioids.
11	THE WITNESS: How would the	11	BY MR. CRAWFORD:
12	company become aware of that information?	12	Q. Right. But you were involved in
13	BY MR. CRAWFORD:	13	at least thinking about it from a regulatory
14	Q. Because the company I mean,	14	standpoint and getting them approved. Right?
15	the company the company sells the drug.	15	You gave a talk on it. Right?
16	Right?	16	MS. HILLYER: Objection to form.
17	A. Okay. The company sells the	17	THE WITNESS: I didn't give a
1 1 0	drug, yes.	18	talk on abuse-deterrent opioids.
18		19	BY MR. CRAWFORD:
19	Q. Right. So it's the company is		
	currently aware that there's an opioid crisis.	20	Q. I thought you did, with regard to
19	currently aware that there's an opioid crisis. Right?		Q. I thought you did, with regard to the difficulties in getting them approved.
19 20 21 22	currently aware that there's an opioid crisis. Right? A. How would	20 21 22	the difficulties in getting them approved. Right?
19 20 21	currently aware that there's an opioid crisis. Right? A. How would MS. HILLYER: Objection to form.	20 21	the difficulties in getting them approved. Right? A. That's incorrect.
19 20 21 22	currently aware that there's an opioid crisis. Right? A. How would	20 21 22	the difficulties in getting them approved. Right?

	Page 201		Page 202
1	A. My talk was about GDUFA and other	1	did know before or the company knew of the
2	barriers. And I think you're referring to Gregg	2	abuse of its opioids that it was selling in the
3	DeRosa's talk.	3	marketplace before the FDA, shouldn't it at least
4	Q. Yeah, DeRosa.	4	put that in its annual report, that there's a
5	But you were present for Mr.	5	safety issue out there?
6	DeRosa's talk. Right?	6	MS. HILLYER: Objection to form.
7	A. I was present, yes.	7	THE WITNESS: Again, we follow
8	Q. So you knew the company was	8	the requirements and we submit to FDA
9	developing abuse-deterrent opioids. Right?	9	what's required to be submitted. The
10	A. Okay.	10	scenario that you're talking about
11	Q. So at some point the company must	11	just it hasn't happened and I've never
12	have known that opioids were being abused.	12	thought about it before and I don't have
13	Right?	13	an opinion on it.
14	MS. HILLYER: Objection to form.	14	BY MR. CRAWFORD:
15	THE WITNESS: As well as FDA.	15	Q. So don't you think, when the FDA
16	BY MR. CRAWFORD:	16	tells you in the approval letter that you're
17	Q. Okay. But I'm just asking at	17	supposed to follow 314.81, and 3148.181
18	some point the company knew. Maybe it knew	18	requires the company to report any safety issues
19	before the FDA knew. Correct?	19	that comes up during a year, you're saying that
20	MS. HILLYER: Objection to form.	20	they don't have to put that in with regard to a
21	THE WITNESS: But maybe it didn't	21	knowledge of an opioid abuse?
22	know before the FDA knew as well.	22	MS. HILLYER: Objection to form.
23	BY MR. CRAWFORD:	23	THE WITNESS: Again, I think as
24	Q. So my hypothetical is, if the FDA	24	we explained in pretty great detail
	Q. So my nypoulousuu 15, 11 ulo 1 271		we explained in pretty great detain
	D 202		
	Page 203		Page 204
1	there, 314.80 and 314.81 are common for	1	Page 204 Q. We just went through that,
1 2		1 2	
	there, 314.80 and 314.81 are common for		Q. We just went through that,
2	there, 314.80 and 314.81 are common for both NDAs and ANDAs and there are certain	2	Q. We just went through that, because they're making an abuse-deterrent opioid.
2 3	there, 314.80 and 314.81 are common for both NDAs and ANDAs and there are certain requirements for NDAs that aren't	2 3	Q. We just went through that, because they're making an abuse-deterrent opioid. Right?
2 3 4	there, 314.80 and 314.81 are common for both NDAs and ANDAs and there are certain requirements for NDAs that aren't expected or required to be submitted for	2 3 4	Q. We just went through that, because they're making an abuse-deterrent opioid. Right? MS. HILLYER: Objection to form.
2 3 4 5	there, 314.80 and 314.81 are common for both NDAs and ANDAs and there are certain requirements for NDAs that aren't expected or required to be submitted for ANDAs.	2 3 4 5	Q. We just went through that, because they're making an abuse-deterrent opioid. Right? MS. HILLYER: Objection to form. THE WITNESS: We just went
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	Page 205		Page 206
1		1	
1	when they're obtained illegally and not	1	Q. Is there any in your view, as
2	used according to the label, but that's	2	a person who has been in the regulatory industry
3	not why Teva would make a product or	3	over 20 years, that there's any regulatory
4	other manufacturers do. They make	4	prohibition for a drug for a generic
5	products because FDA has determined them	5	manufacturer to go out, you know, when there's no
6	to be safe and effective. They're a very	6	REMS, to go out and educate doctors in the proper
7	effective treatment for people who need	7	use of their drugs?
8	management of pain for these types of	8	A. I'm not certain.
9	things.	9	MS. HILLYER: Objection to form.
10	BY MR. CRAWFORD:	10	We've been going about an hour.
11	Q. So once when Teva learned that	11	MR. CRAWFORD: Do you want to
12	their products are being abused, don't they	12	take a quick break?
13	doesn't the company have some obligation to go	13	MS. HILLYER: Sure.
14	out and try to tell doctors how to properly use	14	MR. CRAWFORD: All right.
15	their products?	15	THE VIDEOGRAPHER: Off the
16	MS. HILLYER: Objection to form.	16	record, 1:38.
17	BY MR. CRAWFORD:	17	
18	Q. In your view?	18	(A recess was taken from
19	MS. HILLYER: Objection to form.	19	1:38 p m. to 1:49 p m.)
20	And now asked and answered about four	20	
21	times.	21	THE VIDEOGRAPHER: We are back on
22	THE WITNESS: I'm not sure what	22	the record at 1:49.
23	else I could say further on this.	23	
24	BY MR. CRAWFORD:	24	(Deposition Exhibit No.
	- 005		
	Page 207		Page 208
1	Teva-Tomsky-11, Letter dated December 6,	1	TEVA, dismissing the case on grounds of
2	Teva-Tomsky-11, Letter dated December 6, 2005, 4 pages, was marked for	2	TEVA, dismissing the case on grounds of unenforceability of the three patents. The
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Teva-Tomsky-11, Letter dated December 6, 2005, 4 pages, was marked for identification.) MS. HILLYER: This is 11. BY MR. CRAWFORD: Q. Exhibit 11 we've marked, it's a December 6, 2005 letter to Teva Pharmaceuticals, attention Philip Erickson. It is from, again, Mr. Buehler at the FDA. And this again, no Bates number, it was pulled from the FDA website. So Mr. Buehler is writing now, approving here oxycodone hydrochloride extended release tablets, 10 milligram, 20 milligram and 40 milligram. I believe the one we just read was the 80 milligram approval. So this is the generic OxyContin at the lower doses. Would you agree? A. Yes. Q. And this gives us some clues. Go to the third page. Mr. Buehler writes, "You have	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	TEVA, dismissing the case on grounds of unenforceability of the three patents. The Agencyis aware of the June 7, 2005 ruling by the U.S. Court of Appeals for the Federal Circuit, affirming the Opinion and Order of the same district court in a related case, issued in favor of Endo Pharmaceutical (Endo). The Federal Circuit ruling, among other things, permanently enjoins Perdue, enforcing the '912, '042 and '295 patents. "The decision on June 7, 2005, as well as the first commercial marketing of the product by Endo on the same day, triggered Endo's 180-day generic drug exclusivity period." Skipping a bit, "Endo's 180-day exclusivity for thisproduct expired on December 4, 2005. Therefore, under Section 505," et cetera, et cetera, "your ANDA is eligible for full approval." So it looks like there was you agree with me a patent litigation which was holding up the marketing of the drug at this

	Page 209		Page 210
1	MS. HILLYER: Objection, lack of	1	identification.)
2	foundation, calls for speculation.	2	,
3	THE WITNESS: It appears so.	3	BY MR. CRAWFORD:
4	BY MR. CRAWFORD:	4	Q. We're marking Exhibit 12.
5	Q. So it looks like, at least in	5	This is an ANDA approval from
6	view at this time of Mr. Buehler, that the	6	Carol Holquist over at the FDA to Actavis
7	decisions rendered in the district and court of	7	Laboratories Florida, Inc., attention Janet
8	appeals allowed Endo to start marketing the drug	8	Vaughn, director of regulatory affairs, dated
9	that they had an exclusivity period, because they	9	well, it looks like on the last page there is an
10	were first to market, that expired and then Teva	10	email dated June 3, 2016 from Kevin Herkenham at
11	was free to start marketing its generic version.	11	the FDA to regulatory affairs US, indicating that
12	Is that how you interpret this?	12	the ANDA had been approved and attaching a PDF
13	A. Yes.	13	copy of the approval letter.
14	Q. Again, this is subject to the	14	So they were notifying, at least
15	reporting requirements of CFR 314.80 to .81 and	15	Actavis here in your view, of the approval of
16	314.98 there in the middle. Correct?	16	this product, which was a hydrocodone bitartrate
17	A. Yes.	17	acetaminophen tablet. Right?
18	Q. Let's go to the next exhibit.	18	A. Yes.
19		19	Q. So that I'm trying to
20	(Deposition Exhibit No.	20	understand.
21	Teva-Tomsky-12, ANDA Approval and email	21	Is that that's Vicodin.
22	dated June 03, 2016, Bates stamped	22	Right? Generic Vicodin? Or Norco? Do you know
23	TEVA_MDL_A_02922022 through	23	what brand product that is?
24	TEVA_MDL_A_02922025, was marked for	24	A. I'm not certain.
	Page 211		Page 212
1	Q. And I'm trying to collaborate	1	A. It's possible, but I'm not
2	or this is Actavis product, so we're talking	2	certain.
3	20 June 2016.	3	Q. In 2016, there are 9,092,709
4	This is right about the time	4	prescriptions of that drug in that year. Right?
5	Actavis was acquired by Teva. Right?	5	A. It appears so, yes.
6	A. Roughly.	6	Q. So this represents, just looking
7	Q. So this product came over from	7	through, by far, the biggest seller of a class II
8	the Actavis group. Right?	8	opioid product by Teva in 2016; is that right?
9	A. It would appear so, yes.	9	MS. HILLYER: Same objection.
10	Q. Do you know if this product is	10	THE WITNESS: Based on this
11	still being marketed?	11	document, it looks like it.
12	A. I'm not certain.	12	BY MR. CRAWFORD:
13	Q. Take a look at Exhibit 2, which	13	Q. So and it's close to a third
14	is that list again, on page 5. I just want to	14	of their total relative it's 9 million out of
15	see if you agree that's the second product listed	15	14.6 million of their Teva class II opioid volume
16	on page 5, which is hydrocodone bitartrate and	16	based on the second page. Right?
17	acetaminophen tablets, class II controlled drug	17	A. So I'm not certain, because the
18	schedule.	18	first page shows 30 million.
19	MS. HILLYER: Objection to form,	19	Q. That's all opioid products. I
20	lack of foundation, calls for	20	understand it that way.
21	speculation.	21	And then the second page is just
22	BY MR. CRAWFORD:	22	the class II Schedule II opioids. Right?
23	Q. Do you think that's the same drug	23	A. Again, I'm not certain. I'm not
	th. a.m. 9	24	familiar with this report.
24	there?	23	rammar with this report.

	Page 213		Page 214
1	Q. Okay. Well, this generic	1	identification.)
2	hydrocodone bitartrate and acetaminophen tablet,	2	
3	that's a class II opioid.	3	BY MR. CRAWFORD:
4	You agree with me on that.	4	Q. So we've marked Exhibit 13.
5	Right?	5	Again, this is a the prior exhibit was
6	A. According to this, yes.	6	TEVA MDL A 02922022.
7	Q. Are you aware if this is still	7	This current one, again, pulled
8	being marketed, this drug?	8	from the FDA website, so it's not Bates stamped.
9	A. I think you just asked me that.	9	This is a February 2004 approval
10	I'm not certain.	10	for oxycodone hydrochloride tablets, 15 milligram
11	Q. All right. I'm sorry. My memory	11	and 30 milligram.
12	sometimes goes as far as what I've asked, so	12	This is a generic Roxicodone.
13	yeah. Okay, thank you.	13	Right?
14	Do you have any kind of knowledge	14	A. That's what it says, yes.
15		15	
16	as you sit here of what Teva's current best	16	
	selling opioid, class II opioid is?		1 0 1
17	MS. HILLYER: Objection to form. THE WITNESS: I do not.	17	end of that third paragraph.
18			Q. Okay. That's good. Yep.
19	BY MR. CRAWFORD:	19	Again, approved pursuant to the
20	Q. Let's go to the next document.	20	CFR 314.80 to 81, and 314.98. Correct?
21		21	MS. HILLYER: Again, I'm just
22	(Deposition Exhibit No.	22	going to object to foundation, among
23	Teva-Tomsky-13, Letter dated February 6,	23	other things. This doesn't even say that
24	2004, 2 pages, was marked for	24	it's Teva.
	Page 215		Page 216
1	BY MR. CRAWFORD:	1	BY MR. CRAWFORD:
2	Q. Well, Amide was acquired at some	2	Q. Right here we have a letter from
3	point by Actavis. Right?	3	Actavis. This is written by Jasmine Shah, VP,
4	MS. HILLYER: Objection to the	4	regulatory and medical affairs, to Mr. Buehler at
5	extent it calls for speculation.	5	the FDA.
6	THE WITNESS: Yeah. I'm not	6	This is Actavis submitting a
7	sure.	7	supplement as a changes being effected to seek
8	BY MR. CRAWFORD:	8	approval for a batch size scale-up from 110,000
9	Q. Again, Mr. Buehler is the one who	9	to 3.5 million tablets for the 15 milligram
10	gave the approval. Right?	10	strength.
11	A. He's the head of the Office of	11	And this would be for the same
12	Generic Drugs, so he signs most of them, yes.	12	ANDA, 76-636, as the Roxicodone approval that we
13	Q. Right. Okay. Let's go to the	13	looked at. Correct?
14	next exhibit.	14	MS. HILLYER: Objection to form.
15	Actually, not that one. Skip	15	THE WITNESS: Yes.
16	that.	16	BY MR. CRAWFORD:
17	So this one.	17	Q. So that's a pretty hefty increase
18		18	in batch size.
l	(Deposition Exhibit No.	19	Would you agree with me on that?
19	(2 of conton Lamon 1 to	-/	
19 20	Teva-Tomsky-14 Letter dated June 25	2.0	VIS HILLYER' Unjection Sorry
20	Teva-Tomsky-14, Letter dated June 25, 2007. Bates stamped TEVA MDL, A 10604467	20	MS. HILLYER: Objection. Sorry. BY MR. CRAWFORD:
20 21	2007, Bates stamped TEVA_MDL_A_10604467	21	BY MR. CRAWFORD:
20 21 22	2007, Bates stamped TEVA_MDL_A_10604467 through TEVA_MDL_A_10604633, was marked	21 22	BY MR. CRAWFORD: Q. From 110,000 to 3.5 million?
20 21	2007, Bates stamped TEVA_MDL_A_10604467	21	BY MR. CRAWFORD:

	Page 217		Page 218
1	more than ten times the original batch	1	Q. That's generally the practice.
2	size, yes.	2	Right?
3	BY MR. CRAWFORD:	3	MS. HILLYER: Objection to form.
4	Q. And why does a manufacturer need	4	THE WITNESS: Yes.
5	to get approval for that type of increase in	5	BY MR. CRAWFORD:
6	batch size?	6	Q. All right. And then go to the
7	A. I mean, the regulations are clear	7	third page. Down at the bottom in bold, it says,
8	in terms of what types of changes need to be	8	"This application may contain documentation
9	submitted to the FDA. So, again, if you're	9	bearing 'Amide Pharmaceutical Inc.' name. Please
10	making any changes that have been previously	10	note that Actavis Totowa LLC has acquired all
11	approved by FDA, and it falls into different	11	rights of Amide Pharmaceuticals Inc., since July
12	filing categories, either an annual report, in	12	27, 2005."
13	this case, a CBE supplement, or sometimes a prior	13	So you'd agree with me that
14	approval supplement.	14	Actavis, at least some Actavis entity, had
15	Q. And CBE can just be done	15	acquired the rights to this product after that
16	unilaterally without preapproval.	16	date?
17	They're just notifying the FDA of	17	MS. HILLYER: Objection to form.
18	the change in case the FDA wants to intervene.	18	BY MR. CRAWFORD:
19	Right?	19	Q. It looks like acquired Amide.
20	MS. HILLYER: Objection to form.	20	Right?
21	THE WITNESS: Generally speaking.	21	A. Yes, it appears so.
22	But typically a company would wait 30	22	Q. So again, do you know if this is
23	days before implementing such a change.	23	a product that's being currently marketed by
24	BY MR. CRAWFORD:	24	Teva?
	Page 219		Page 220
1	Page 219 A. I do not.	1	Page 220 exhibit.
1 2		1 2	
	A. I do not.		
2	A. I do not.Q. I'm just trying to triangulate it	2	exhibit.
2 3	A. I do not.Q. I'm just trying to triangulate it here with the chart that we have.	2 3	exhibit (Deposition Exhibit No.
2 3 4	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would	2 3 4	exhibit (Deposition Exhibit No. Teva-Tomsky-15, Supplement History
2 3 4 5	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you	2 3 4 5	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5
2 3 4 5 6	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2?	2 3 4 5 6	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657
2 3 4 5 6 7	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah.	2 3 4 5 6 7	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked
2 3 4 5 6 7 8	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah. BY MR. CRAWFORD:	2 3 4 5 6 7 8	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked
2 3 4 5 6 7 8	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. There is an oxycodone	2 3 4 5 6 7 8 9	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked for identification.)
2 3 4 5 6 7 8 9	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. There is an oxycodone hydrochloride tablet, generic Roxicodone, listed	2 3 4 5 6 7 8 9	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked for identification.) MS. HILLYER: Sorry. What
2 3 4 5 6 7 8 9 10	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. There is an oxycodone hydrochloride tablet, generic Roxicodone, listed in the middle of exhibit page 18.	2 3 4 5 6 7 8 9 10	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked for identification.) MS. HILLYER: Sorry. What number?
2 3 4 5 6 7 8 9 10 11	A. I do not. Q. I'm just trying to triangulate it here with the chart that we have. If you look at page 8, would you MS. HILLYER: Of Exhibit 2? MR. CRAWFORD: Yeah. BY MR. CRAWFORD: Q. There is an oxycodone hydrochloride tablet, generic Roxicodone, listed in the middle of exhibit page 18. And it starts up in 2016, which,	2 3 4 5 6 7 8 9 10 11	exhibit. (Deposition Exhibit No. Teva-Tomsky-15, Supplement History Oxycodone Hydrochloride Tablets USP, 5 mg, 15 mg and 30 mg, TEVA_MDL_A_10602657 through TEVA_MDL_A_10602670, was marked for identification.) MS. HILLYER: Sorry. What number? MR. CRAWFORD: 14.
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Page 222 Page 221 1 MR. CRAWFORD: Yeah. 1 fairly recently. And I'm just trying to find out 2 2 THE WITNESS: It appears to be. if there's -- if you wanted, as the head of the 3 3 US generics regulatory, a supplement history, how BY MR. CRAWFORD: 4 Q. Okay. And so tell me what a 4 would you go about doing that? 5 supplement -- have you ever seen one of these 5 A. I would ask the person who's reports before? 6 responsible for this product to provide it to me. 6 7 7 Q. Is there an FDA contact log that A. No. 8 8 Do you know if there's any way to you're aware of that the company keeps? 9 generate within Teva currently a report of all 9 A. So there's -- typically, I would guess those documents or any FDA contacts would 10 the supplement activity with regard to a 10 11 be saved -- actually, now they're just saved in 11 particular drug? 12 12 MS. HILLYER: Objection to form. 13 THE WITNESS: Yeah. I'm not 13 But prior to current practices, I 14 think there was -- there was a -- hard copies 14 certain. I haven't seen it. And I'm not 15 certain how it was pulled. It could have 15 that were kept in binders. 16 been manually put together. 16 Q. So there's no database of FDA 17 BY MR. CRAWFORD: 17 contacts that you're aware of? 18 Q. But you don't know for sure? You 18 A. No, not that I'm aware of. 19 don't -- you don't know whether it was manually 19 Q. So it's just kept in people's 20 20 email boxes, if they get one. And if you want to put together or generated somehow? 21 A. Yeah. I'm not certain. 21 look it up, you've got to go through people's 22 Q. If you look at the last page, 22 emails? 23 it's 12/12/17 is one of the dates for labeling 23 A. Correct. Sometimes that information would be kept in the global 24 CBE. So this looks like it was put together 24 Page 223 Page 224 regulatory affairs database. So it would just be 1 1 And is that in like a database or Q. 2 a line item that there was a call with FDA on 2 something? 3 such and such a date and this is the contents of 3 A. Yes. It's the global regulatory affairs database. It's called Global Insight. 4 what was discussed. But I'm not sure if it would 4 5 be in detailed form. You would have to pull the 5 Q. And so if you wanted to get all the written exchanges between the FDA for a 6 actual email to find that information. 6 7 7 particular drug, is there a way to kind of filter Q. For the supplement submissions 8 and contacts, is that information kept in kind of 8 the database for that? 9 a single place in the company for each drug? 9 A. It's pretty difficult. I think I 10 Sorry, can you repeat your 10 alluded to it earlier. The global regulatory A. 11 question? 11 database is pretty challenging to navigate and 12 Q. Like for supplemental ANDAs and 12 even get reports ran, so that's why teams wind up tracking them for purposes of keeping them in one 13 13 keeping a lot of their own manual tracking place, is there a place where information like sheets. So it's possible, again, that this came 14 14 15 that is kept? 15 from a manual tracking sheet that somebody was 16 A. So again, all the information 16 doing. 17 would be saved in the product shared drive. And 17 Q. All right. Let's go to the next then in the global regulatory affairs database, 18 18 document. 19 every submission that goes to FDA, as well as 19 20 correspondence that come back to FDA, is entered 20 (Deposition Exhibit No. 21 and logged into that database. 21 Teva-Tomsky-16, Periodic Adverse Drug 22 22 Q. So there is a log of Experience Report, ANDA: 076636, 23 correspondence that goes back and forth? 23 TEVA MDL A 11065997 through 24 A. Yes. 24 TEVA MDL A 11066038, was marked for

	Page 225		Page 226
1	identification.)	1	Q. That's a separate type of report?
2		2	A. Yes.
3	BY MR. CRAWFORD:	3	Q. And this pretty much just lists
4	Q. So we've marked Exhibit 16, which	4	adverse events in prior 15-day reports and so on
5	is a periodic adverse drug experience report for	5	that were discovered throughout the year. Right?
6	the reporting period March 1, 2017 to February	6	A. That's correct.
7	28, 2018. It's for ANDA 076-636.	7	Q. And then who let's see.
8	Again, this would be the generic	8	Is this report signed or verified
9	Roxicodone product that we have been discussing	9	by anybody in the company?
10	the past few exhibits. Correct?	10	A. Yeah. I'm not certain. This is
11	A. Yes, it appears so.	11	a report that's put together by the
12	Q. All right. This is called a	12	pharmacovigilance team, but I would think that
13	PADER, right, P-A-D-E-R?	13	there would be a cover letter on this at least.
14	A. That's correct.	14	Q. So it was prepared in Zagreb,
15	Q. And are these the reports	15	right, in Croatia?
16	submitted pursuant to Section 314.80?	16	A. That's what it says, yes.
17	A. That's correct.	17	Q. And what group
18	Q. And this is now I guess an	18	It's the Teva periodic reports
19	annual report at this stage of the marketing of	19	and risk management center global patient safety
20	the drug. Right?	20	and pharmacovigilance group there that put this
21	A. That's correct.	21	together?
22	Q. But it's not the annual report	22	A. That's what it says, yes.
23	that's submitted for 314.81. Correct?	23	Q. This isn't a Teva USA company
24	A. That's correct.	24	that put this together. Right?
	Page 227		Dama 220
	1430 227		Page 228
1	MS. HILLYER: Objection to form,	1	A. Which annual report? Are you
1 2	5	1 2	_
	MS. HILLYER: Objection to form,		A. Which annual report? Are you
2	MS. HILLYER: Objection to form, lack of foundation.	2	A. Which annual report? Are you talking about 314.80 or 314.81?
2	MS. HILLYER: Objection to form, lack of foundation. THE WITNESS: Yeah. I'm not sure	2	A. Which annual report? Are you talking about 314.80 or 314.81? Q. 81.
2 3 4	MS. HILLYER: Objection to form, lack of foundation. THE WITNESS: Yeah. I'm not sure who the legal entity is.	2 3 4	A. Which annual report? Are you talking about 314.80 or 314.81? Q. 81. A. 314.81, the practice currently?
2 3 4 5	MS. HILLYER: Objection to form, lack of foundation. THE WITNESS: Yeah. I'm not sure who the legal entity is. BY MR. CRAWFORD:	2 3 4 5	A. Which annual report? Are you talking about 314.80 or 314.81? Q. 81. A. 314.81, the practice currently? Q. Yes.
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2 3 4 5 6 7	MS. HILLYER: Objection to form, lack of foundation. THE WITNESS: Yeah. I'm not sure who the legal entity is. BY MR. CRAWFORD: Q. But it's Teva. Right? It's a Teva company? A. Yes. Q. Are these reports generally, the	2 3 4 5 6 7	A. Which annual report? Are you talking about 314.80 or 314.81? Q. 81. A. 314.81, the practice currently? Q. Yes. A. Because the majority of them would be signed off in India. Q. I got it. Is that by a Teva entity in
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	Page 229		Page 230
1	are for addiction to opioids, drug dependence.	1	BY MR. CRAWFORD:
2	Do you see those two at the	2	Q page 35, there is a report of
3	bottom?	3	some type of drug misuse here, where oxycodone at
4	A. Yes.	4	least was one of the drugs that the patient was
5	Q. So serious they're not	5	taking. Right?
6	reported within the 15 days because addiction is	6	MS. HILLYER: Objection to form.
7	a side effect already in the label. Right?	7	THE WITNESS: Which one are you
8	A. Correct. That's my	8	looking at?
9	understanding.	9	BY MR. CRAWFORD:
10	Q. But it's considered serious.	10	Q. The first one.
11	Serious is a defined term of art.	11	A. I see several drugs, including
12	Right?	12	heroin, so
13	A. Yes.	13	Q. Right. And oxycodone is one of
14	Q. So serious means what does it	14	the drugs, too. Right?
15	mean, hospitalization, death or affecting	15	A. Yes.
16	pregnancy or something like that?	16	Q. Do you have any idea how many
17	A. I'm not certain.	17	people who use heroin started on prescription
18	Q. So but addiction does fall	18	opioids, what the statistic is on that from the
19	whatever under regulatory definition of serious.	19	CDC?
20	Right?	20	MS. HILLYER: Objection to form.
21	A. It appears so, yes.	21	THE WITNESS: I do not.
22	Q. And then moving on to	22	BY MR. CRAWFORD:
23	MS. HILLYER: I'm sorry,	23	Q. Would 80 percent surprise you?
24	objection to form on the last one.	24	MS. HILLYER: Objection to form.
	Page 231		Page 232
1	THE WITNESS: I've never heard	1	puts these together.
2	any of those statistics, so I'm not	2	BY MR. CRAWFORD:
3	familiar with it.	3	Q. But this is submitted to the FDA.
4	BY MR. CRAWFORD:	4	Right?
5	Q. So the source says, "Spontaneous,	5	A. Yes. And as we discussed
6	health authority, patient-consumer."	6	earlier, the regulatory affairs team manages the
7	That just means that this report	7	new ANDA submissions and then the post-approval
8	came into the company, Teva, through either a	8	supplements and annual reports, but the
9	healthcare provider or a patient or a patient	9	pharmacovigilance team manages the drug safety
10	family member. Right?	10	reports.
11	MS. HILLYER: Objection, lack of	11	Q. So they interface with the FDA
12	foundation, calls for speculation. He's	12	directly on these reports?
13	testified these reports don't come	13	A. Yes.
14	through them.	14	Q. Understood.
15	BY MR. CRAWFORD:	15	But do you know what a
16	Q. Where did this report does	16	spontaneous report is, right, in the regulatory
17	this source of the report listed here give you	17	parlance?
18	any idea what the potential source was of the	18	A. Generally speaking.
19	report?	19	Q. Okay. What's your understanding
20	MS. HILLYER: Same objections.	20	of a spontaneous report?
21	THE WITNESS: Again, I'm not	21	A. When a company receives or when
22	familiar with this report, how things are	22	anybody receives a report of an adverse event
23	categorized, what this means. I have no	23	with a product. Q. Let's go to the next doc.
24		. /4	Q. Let's go to the next doc.
2 1	responsibility for these or the team that		Q. Let's go to the next doe.

	Page 233		Page 234
1	Actually, hold on.	1	knowledge, do you know if this is a drug that is
2	Well, okay, let's mark it.	2	currently being marketed by the company?
3		3	A. I do not.
4	(Deposition Exhibit No.	4	Q. Let's go to the next exhibit.
5	Teva-Tomsky-17, Letter dated 07/11/2013,	5	
6	Bates stamped Acquired Actavis 00677901	6	(Deposition Exhibit No.
7	through Acquired_Actavis_00677905, was	7	Teva-Tomsky-18, Letter dated August 17,
8	marked for identification.)	8	2011, Bates stamped TEVA MDL A 10662653
9	marked for identification.)	9	through TEVA_MDL_A_10662655, was marked
10	BY MR. CRAWFORD:	10	for identification.)
11	Q. Okay. We've marked Exhibit 17,	11	
12	which is Bates Acquired Actavis_00677901.	12	BY MR. CRAWFORD:
13	It's an approval letter to for	13	Q. Again, this is we marked
14	ANDA 079-046 dated July 11, 2013, written to	14	another approval letter here,
15	Actavis Elizabeth LLC by Kathleen Uhl at the FDA,	15	TEVA_MDL_A_10662653. It is ANDA number 076-709
16	U-H-L. And it's granting final approval of the	16	for the fentanyl transdermal system.
17	oxymorphone hydrochloride extended release	17	This again would be an approval
18	tablet.	18	letter for
19	That's again generic Opana ER.	19	A. This isn't an approval letter, at
20	Right?	20	least
21	A. Correct.	21	
22	Q. And do you know if this drug	22	Q. You're right. It's approving it's submitting an electronic REMS. Right?
23		23	A. Correct.
24	is and I understand you've said that you don't know a lot of the drugs, but just personal	24	Q. But this would have been for a
24	know a fot of the drugs, but Just personal	24	Q. But this would have been for a
	D 025		
	Page 235		Page 236
1	product that was approved. Right?	1	Page 236 Laboratories FL Inc. It's from Vincent Samsone
1 2		1 2	
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2 3 4 5 6	product that was approved. Right? A. I mean, I'm not certain. I would have to go back and look at the entire history. Q. Right. I could not find the approval letter. But are you aware if Teva is	2 3 4 5 6	Laboratories FL Inc. It's from Vincent Samsone from the FDA. So this is an approval letter for generic Abstral. Right? A. That's what the letter states, yes.
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	Page 237		Page 238
1	BY MR. CRAWFORD:	1	dependent on what product the what application
2	Q. This is an approval letter for	2	the product is being manufactured under.
3	morphine sulfate extended release capsules.	3	Q. So if it was being manufactured
4	I think it's for the brand name	4	under an NDA let's take a hypothetical.
5	Kadian. Correct?	5	So it was being manufactured for
6	A. I am not certain by this letter.	6	an NDA holder by Teva, who would be responsible
7	Q. Do you know are you aware if	7	for the regulatory submissions, the annual
8	Teva manufactures, markets or sells Kadian or a	8	reports and PADERs?
9	generic version of Kadian?	9	A. So if it's being manufactured
10	A. Yeah. I'm not certain.	10	under the NDA, meaning the NDA holder would have
11	Q. Is it possible that Teva	11	filed a site change to, say, an ANDA holder, the
12	currently manufactures Kadian for Allergan at	12	information would be filed to the NDA.
13	this point in time?	13	Q. So that means the NDA holder is
14	A. I'm not certain.	14	filing it with the FDA?
15	Q. If Teva manufactured a product	15	A. Yes.
16	for another company who is the NDA holder or an	16	Q. All right. Let's do this next
17	ANDA holder and that company distributed it, who	17	document here.
18	would be responsible for making the regulatory	18	
19	submissions on that drug?	19	(Deposition Exhibit No.
20	MS. HILLYER: Objection to form.	20	Teva-Tomsky-21, Industry Meeting to
21	BY MR. CRAWFORD:	21	Discuss Opioid Analgesics REMS, 7 pages,
22	Q. Do you know? Is there kind of a	22	was marked for identification.)
23	general rule?	23	,
24	A. It would have to it would be	24	BY MR. CRAWFORD:
1		1	the record.
1	Q. So we marked again, this	T	the record.
	didn't some from the Tayo production but it's	2	THE VIDEOCD ADHED. Off the
2	didn't come from the Teva production, but it's	2	THE VIDEOGRAPHER: Off the
3	called, "Industry Meeting to Discuss Opioid	3	THE VIDEOGRAPHER: Off the record, 2:28.
3 4	called, "Industry Meeting to Discuss Opioid Analgesics REMS." It's Exhibit 21.	3 4	record, 2:28.
3 4 5	called, "Industry Meeting to Discuss Opioid Analgesics REMS." It's Exhibit 21. It's minutes of a meeting held	3 4 5	record, 2:28 (A recess was taken from
3 4 5 6	called, "Industry Meeting to Discuss Opioid Analgesics REMS." It's Exhibit 21. It's minutes of a meeting held January 25, 2017. It looks like it was attended	3 4 5 6	record, 2:28. (A recess was taken from 2:28 p m. to 2:46 p m.)
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	called, "Industry Meeting to Discuss Opioid Analgesics REMS." It's Exhibit 21. It's minutes of a meeting held January 25, 2017. It looks like it was attended by members of the FDA and other organizations, and then members of industry regarding opioid analgesics REMS. Had you heard about this meeting occurring? A. It's not familiar to me. Q. I see that there's no Actavis or Teva attendee. I'm just wondering why, if you know, why they didn't attend this meeting? A. No, I'm not certain. Q. Who was head of the REMS group there at the time at Teva? A. Again, it would have been Kishore Gopu, who we discussed earlier. MR. CRAWFORD: Take a minute or	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	record, 2:28. (A recess was taken from 2:28 p m. to 2:46 p m.) THE VIDEOGRAPHER: We are back on the record at 2:46. (Deposition Exhibit No. Teva-Tomsky-22, Email chain, top one dated 1/9/2017, Bates stamped TEVA_MDL_A_09655240 through TEVA_MDL_A_09655244, was marked for identification.) PROPERTY OF THE PROPERTY O

	Page 241		Page 242
1	Fee Clean-Up. Attachments: All Teva Companies	1	the purposes of calculating the fees.
2	and Product ANDA numbers" in an Excel	2	You wouldn't have to have, like
3	spreadsheet.	3	if you got 20 different ANDA holders that are all
4	So this is just the email chain.	4	owned by the same company, you didn't have to pay
5	Can you tell me what this	5	20 different fees. Right?
6	interchange was about, as you recall?	6	A. Yes.
7	A. Sure. As I recall, under the	7	Q. And so what you're doing here is
8	Generic Drug User Fee Act, GDUFA II, FDA began	8	you're trying to compile all the various legacy
9	charging a program fee based on the number of	9	entities and the ANDAs that you hold and you're
10	approved applications per company.	10	trying to get that list generated. Right?
11	And there was three different	11	A. That's correct.
12	buckets. There was small, medium and large.	12	Q. And did you successfully get that
13	Anybody with more than 20 approved applications	13	list?
14	was considered to pay the large fee.	14	A. Yes.
15	But it's not like each applicant	15	O. And who's Brenda did Ms.
16	holder had to pay a fee. For example, Actavis	16	Hunsberger send that list?
17	didn't have to pay and Teva and Watson. So you	17	A. So she's no longer with the
18	can claim all those companies under the Teva	18	company. Currently it's done by someone named
19	affiliate.	19	Megan Hughes.
20	So the purpose of this was to	20	Q. What department is she in?
21	make sure that we collected all the different	21	A. It's in regulatory, it's called
22	applicants and put them under the bucket of Teva.	22	the regulatory information management.
23	Q. So you can say that a family of	23	Q. Are they based in Parsippany?
24	related companies could be compiled together for	24	A. Currently she's based in Frazer.
	Tomate Companies Companies together for		
	Page 243		Page 244
1	Eventually, this position will be located in	1	process, was they gave you access to this, the
2	Parsippany.	2	FDA?
3	Q. So this list that's attached is	3	A. That's correct.
4	basically just a list I haven't attached it,	4	Q. Is the public able to download
5	it's a huge spreadsheet.	5	this?
6	But to me, tell me if this is	6	A. Yes.
7	accurate, it's a list of all the Teva-related	7	Q. So but who made the decision
8			
	companies, including the Actavis entities,	8	or figured out what entities were Teva-related
9	Watson, Ivax, Barr, ones that they've acquired in	9	or figured out what entities were Teva-related entities? Was that Ms. Hunsberger's department?
9 10	Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and		_
10 11	Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and drug name below each company.	9 10 11	entities? Was that Ms. Hunsberger's department? A. No. It was a compilation of several people. We worked with lawyers as well
10	Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and drug name below each company. Is that what's being compiled	9	entities? Was that Ms. Hunsberger's department? A. No. It was a compilation of several people. We worked with lawyers as well to make sure that we were capturing all the Teva
10 11	Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and drug name below each company.	9 10 11	entities? Was that Ms. Hunsberger's department? A. No. It was a compilation of several people. We worked with lawyers as well to make sure that we were capturing all the Teva entities.
10 11 12	Watson, Ivax, Barr, ones that they've acquired in the past, and then there are ANDA numbers and drug name below each company. Is that what's being compiled here? A. Generally speaking, yes. This is	9 10 11 12	entities? Was that Ms. Hunsberger's department? A. No. It was a compilation of several people. We worked with lawyers as well to make sure that we were capturing all the Teva entities. Q. And do you feel that this final
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	Page 245		Page 246
1	have one brief redirect.	1	neither.
2		2	MS. HILLYER: Do we have to go
3	EXAMINATION	3	off the record to swap?
4	LAAMINATION	4	THE VIDEOGRAPHER: Yep, please.
5	BY MS. HILLYER:	5	Going off the record, 2:52.
6	Q. Earlier in response to Mr.	6	Going off the record, 2.32.
7	Crawford's questioning, you were talking about	7	(A discussion off the record
			•
8	conversations you had with an individual in	8	occurred.)
9	Israel.	9	THE HIDEOGRAPHED W. 1 1
10	Do you recall that?	10	THE VIDEOGRAPHER: We are back on
11	A. Yes.	11	the record at 2:53.
12	Q. And you mentioned that the	12	
13	substance or the basis for those conversations	13	EXAMINATION
14	was the product filings prepared for the US.	14	
15	Do you recall that?	15	BY MR. GASTEEL:
16	A. Yes.	16	Q. Good afternoon, Mr. Tomsky. My
17	Q. Were any of those products opioid	17	name is Ben Gasteel. I represent a group of
18	products?	18	plaintiffs in the state of Tennessee who are
19	A. No. Because all the opioid	19	pursuing cases that are slightly different than
20	products are manufactured in the US. And the	20	the cases that Mr. Crawford had been asking you
21	Israel team had nothing to do with those.	21	questions throughout the day.
22	MS. HILLYER: I have no further	22	I'm going to go I'm not going
23	questions at this time.	23	to spend as much time as Mr. Crawford did today,
24	MR. CRAWFORD: All right. Me	24	so hopefully we can get out of here relatively
	Page 247		Page 248
1	quickly.	1	correspondence later in the month where
2	I'm going to do my best not to	2	we told you that we did not cross-notice
3	cover anything that Mr. Crawford covered, but	3	Mr. Tomsky in the Tennessee action and we
4	there might be a little bit of overlap.	4	objected to your questioning him here.
5	I want to begin, you testified	5	And there was no response received from
6	earlier about giving a deposition last week in a	6	your firm.
7	case?	7	So I understand that, you know,
8	MS. HILLYER: Sorry, Ben, before	8	you and I talked earlier off the record
9	you get too far into your questions, I	9	that you guys believe you sent the
10	just want to place some objections on the	10	cross-notice. Setting that aside, I'm
11	record	11	going to allow you guys to go ahead with
12	MR. GASTEEL: Sure.	12	questioning Mr. Tomsky over our
13	MS. HILLYER: as I know you	13	objection, both to the relevancy of his
14	probably expected.	14	deposition and procedurally how we got to
15	So we did not or the key	15	being here, but with the understanding
16	people relevant to working on the	16	that, you know, as the Tennessee case
17	Tennessee case from my firm did not	17	proceeds, to the extent you later seek to
18	receive the cross-notice that you told me	18	depose Mr. Tomsky, we're going to say
19	about today.	19	that this was your opportunity to do that
20	I understand that your firm was	20	and we've now given you that and we'll
21	informed earlier this month about who	21	give you the opportunity to do that.
22	should be on the notification list.	22	MR. GASTEEL: So I'll just say
44			· · · · · · · · · · · · · · · · · · ·
2.2	Those meenle were not on the notification	7.2	yery chartly in reconnect that we think
23 24	Those people were not on the notification list. And then there was subsequent	23 24	very shortly in response that we think that we've properly cross-noticed Mr.

	Page 249		Page 250
1	Tomsky in the deposition. And to the	1	A. I believe so.
2	extent that, you know, we may need to	2	Q. Was it a Teva product that the
3	talk to him again, we'll continue to	3	plaintiff took that resulted in that lawsuit?
4	reserve that right. But we're certainly	4	A. Allegedly.
5	here willing and able to ask him some	5	Q. Mr. Crawford had previously asked
6	questions today.	6	you some questions about the current opioid
7	MS. HILLYER: Understood.	7	epidemic and crisis that's going on in this
8	BY MR. GASTEEL:	8	country.
9	Q. With all of that out of the way,	9	Do you recall some of that
10	Mr. Tomsky, you talked earlier today about giving	10	testimony?
11	a deposition last week in an opioid-related case.	11	A. Yes.
12	Do you recall that?	12	Q. Can you clarify, because I wasn't
13	A. Yes.	13	sure about your testimony.
14	Q. Do you recall the name of the	14	As VP of regulatory affairs of
15	plaintiff in that case?	15	generics at Teva, you knew that there was a
16	A. I believe it was Guevnos.	16	problem with abuse and misuse of prescription
17	Q. I don't suppose you know how to	17	opioids throughout the country. Right?
18	spell that?	18	MS. HILLYER: Objection to form.
19	A. I could try. I think it's	19	THE WITNESS: I wouldn't say I
20	G-U-E-V-N-O-S.	20	necessarily agree with that statement.
21	Q. And do you know if that case was	21	Can you reword?
22	pending in federal or state court?	22	BY MR. GASTEEL:
23	A. I'm not certain.	23	Q. Well, do you believe that there
24	Q. Is Teva a defendant in that case?	24	is a prescription opioid epidemic in this country
	Page 251		Page 252
1	right now?	1	yourself as to the places that were particularly
2	A. I believe there is an opioid	2	prone to abuse and misuse of prescription
3	epidemic related to the misuse and illicit use of	3	opioids?
1			•
4	drugs.	4	MS. HILLYER: Same objection.
4 5	Q. And that would include		MS. HILLYER: Same objection. THE WITNESS: No.
5 6	Q. And that would include prescription opioids?	4 5 6	MS. HILLYER: Same objection. THE WITNESS: No. BY MR. GASTEEL:
5 6 7	Q. And that would include prescription opioids?A. Prescription opioids when they're	4 5 6 7	MS. HILLYER: Same objection. THE WITNESS: No. BY MR. GASTEEL: Q. While working with Teva as the VP
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And that would include prescription opioids? A. Prescription opioids when they're obtained not from a prescriber or healthcare professional or what have you. Q. And that would be an example of an abuse or a misuse of a prescription opioid. Right? A. Illicit misuse, yes. MS. HILLYER: Ben, can you speak up? MR. GASTEEL: Sure. BY MR. GASTEEL: Q. Did you ever try to educate yourself as to the reasons why there was large scale abuse and misuse of prescription opioids? MS. HILLYER: Objection to form. THE WITNESS: No, I did not.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. HILLYER: Same objection. THE WITNESS: No. BY MR. GASTEEL: Q. While working with Teva as the VP of regulatory affairs generics, did you investigate at all the amount of Teva-produced generic opioids that were filling prescriptions in this country? A. No. MS. HILLYER: Objection to the form. BY MR. GASTEEL: Q. Prior to joining Teva, do you recall having any knowledge about abuse and misuse of prescription opioids? A. No. Q. Did the companies that you worked for prior to Teva manufacture or produce prescription opioids?

	Page 253		Page 254
1	they are actively manufacturing them or	1	Q. And the email is forwarding an
2	distributing them, I am not certain.	2	email from the previous day.
3	Q. But they had at least an NDA or	3	Do you see that?
4	an ANDA to make them?	4	A. Yes.
5	A. They had an ANDA.	5	Q. From a Mark Hendricks (sic) at
6		6	the GPHA?
7	(Deposition Exhibit No.	7	A. Yes.
8	Teva-Tomsky-23, Email chain, top one	8	Q. What is the GPHA?
9	dated September 11, 2013, Bates stamped	9	A. The Generic Pharmaceutical
10	TEVA_MDL_A_11584417 through	10	Association.
11	TEVA MDL A 11584419, was marked for	11	Q. Is that a trade group that Teva
12	identification.)	12	is part of?
13		13	A. Yes.
14	BY MR. GASTEEL:	14	Q. And do they help Teva monitor
15	Q. I hand you a document that we'll	15	what's going on at the FDA?
16	mark as Exhibit 23.	16	MS. HILLYER: Objection.
17	MS. HILLYER: Take your time to	17	BY MR. GASTEEL:
18	look it over.	18	Q. With regard to generic
19	THE WITNESS: Okay.	19	medications?
20	BY MR. GASTEEL:	20	MS. HILLYER: Objection to form.
21	Q. Do you see that this is an email	21	THE WITNESS: They're a generic
22	from Gary Buehler to a variety of people,	22	trade association and, sure, they help
23	including you, on September 11, 2013?	23	disseminate information that's relevant
24	A. Yes.	24	to the generic industry.
			Ç
	D 0FF		
	Page 255		Page 256
1	BY MR. GASTEEL:	1	Page 256 and post market studies to combat the crisis of
1 2		1 2	
	BY MR. GASTEEL:		and post market studies to combat the crisis of
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	Page 257		Page 258
1	MS. HILLYER: The very last	1	MS. HILLYER: I think he's here.
2	paragraph?	2	THE WITNESS: Oh, okay.
3	MR. GASTEEL: It's the last thing	3	Yes.
4	in the email above the signature block.	4	BY MR. GASTEEL:
5	THE WITNESS: Okay.	5	Q. Do you recall when the FDA
6	BY MR. GASTEEL:	6	required these safety labeling changes?
7	Q. Do you see that?	7	A. I'm not certain.
8	A. Yes.	8	Q. Do you know if Teva added that
9	Q. Do you know if Teva received the	9	label to its generic opioids at that time?
10	letter that was referenced in this email?	10	MS. HILLYER: Objection to form.
11		11	THE WITNESS: Again, as I had
12	A. Either way. I mean, via this	12	testified earlier, I mean, we monitor the
	email itself they would have received this		
13	letter.	13	FDA's website for labeling updates and
14	Q. And then the email goes on, I	14	revisions and to keep our labeling in
15	believe, in the fifth paragraph down, beginning,	15	line with the branded drug or the
16	"A safety labeling change was instituted."	16	reference listed drug holder.
17	Do you see that?	17	BY MR. GASTEEL:
18	A. Yes.	18	Q. And according to this email, Teva
19	Q. And it goes on to talk about new	19	would have at least had knowledge as of September
20	requirements for a boxed warning of it says	20	of 2013 that the FDA commissioner thought that
21	addition, but I think it's meant to say	21	there was an opioid crisis of misuse, abuse,
22	addiction, "abuse, and misuse, which can lead to	22	addiction, overdose and death. Correct?
23	overdose and death."	23	MS. HILLYER: Objection to form.
24	Do you see that?	24	THE WITNESS: Sorry, can you
	Davis 250		Davis 200
	Page 259		Page 260
_		1	m 1 1 2 24 42
1	repeat your question?	1	Take as much time with this
2	BY MR. GASTEEL:	2	document, sir, my question is going to be whether
2 3	BY MR. GASTEEL: Q. Sure.	2 3	document, sir, my question is going to be whether or not you recall receiving this email.
2 3 4	BY MR. GASTEEL: Q. Sure. It says, according to this email,	2 3 4	document, sir, my question is going to be whether or not you recall receiving this email. A. I mean, it doesn't stand out to
2 3 4 5	BY MR. GASTEEL: Q. Sure. It says, according to this email, Teva would have at least had knowledge as of	2 3 4 5	document, sir, my question is going to be whether or not you recall receiving this email. A. I mean, it doesn't stand out to me that I recall immediately when we received it,
2 3 4 5 6	BY MR. GASTEEL: Q. Sure. It says, according to this email, Teva would have at least had knowledge as of September of 2013 that the FDA commissioner	2 3 4 5 6	document, sir, my question is going to be whether or not you recall receiving this email. A. I mean, it doesn't stand out to me that I recall immediately when we received it, but sure, I mean, I'm on the email.
2 3 4 5 6 7	BY MR. GASTEEL: Q. Sure. It says, according to this email, Teva would have at least had knowledge as of September of 2013 that the FDA commissioner thought there was an opioid crisis of misuse,	2 3 4 5 6 7	document, sir, my question is going to be whether or not you recall receiving this email. A. I mean, it doesn't stand out to me that I recall immediately when we received it, but sure, I mean, I'm on the email. Q. Any reason to doubt that you
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Page 261 Page 262 1 THE WITNESS: Yes. 1 I want to flip to what I think is BY MR. GASTEEL: 2 2 the second page of that document. It's the email 3 Q. And do you take positions on 3 from Gina Elton to a variety of people, including you, on Tuesday, October 29, 2013. 4 citizen's petitions? In other words, does Teva 4 5 file responses to citizen's petitions? 5 Do you see that? 6 A. I would say generally speaking we A. Yes. 6 7 don't. These are petitions that are filed to FDA 7 Q. And it says, "FYI -- this CP was on our Watch List." 8 for FDA to opine on. There may have been cases 8 9 in the past where Teva has felt the need to 9 Did I read that correctly? 10 respond to one, but generally speaking we 10 11 typically don't respond to these citizen's Q. Do you know what that reference 11 12 petitions. 12 to "on our Watch List" means? 13 Is it regulatory affairs that 13 A. No. I mean, I believe it has to Q. tracks these citizen's petitions? do with products -- if we have a pending or 14 14 15 A. So, at this time, it would have 15 approved products, therefore, we would want to 16 the regulatory intelligence and policy group. 16 look at any citizen's petitions filed for any of 17 Q. And who in the regulatory 17 our pending or approved products. Q. And then if you flip to the next 18 intelligence and policy group would have been 18 responsible for tracking FDA petitions at this 19 19 page, the email kind of gives a brief summary of 20 time? 20 what the citizen's petition sets forth. 21 It would be Gary Buehler or it 21 Do you see that? A. A. Yes. 22 was also Gina Elton who was a part of his team 22 23 who is on this email. 23 Q. And then I want to begin with the paragraph, it's kind of the last paragraph. It 24 O. Great. 24 Page 263 Page 264 says, "The CP opens with a discussion." 1 1 decisions made by the FDA regarding these 2 Okay. 2 A. products." 3 Q. Do you see that? 3 Did I read that correctly? And it says the CP -- and that's 4 4 Yes. 5 a reference to the citizen's petition. Right? 5 And then it states, "While they applauded the oxycodone decision, they were 6 That's correct. 6 7 "The citizen's petition opens 7 highly critical of the oxymorphone and 8 with a discussion of the current status of the 8 buprenorphine implant decisions." 9 abuse epidemic and the current administration's 9 Did I read that correctly? 10 policy towards this problem." 10 A. Yes. 11 Did I read that correctly? 11 Q. And then they state, and then it 12 A. Yes. 12 goes on to state, "They state tat" -- I think it's supposed to be that -- "recent FDA actions 13 And then it goes on to detail 13 some of the products that are referenced in indicate that the FDA is not acting in a manner 14 14 15 15 that adequately reflects the urgency of the there. 16 Do you see the sentence 16 prescription drug abuse epidemic, and that the 17 beginning, "Numerous other initiatives from other 17 FDA is not optimally exercising its regulatory 18 Federal agencies"? Or I'm sorry, the sentence 18 authority to enhance the Obama" Administration's 19 that begins, "The CP then discusses the specific 19 policies. 20 products." 20 Did I read that correctly? 21 A. Yes. 2.1 A. Yes. 22 Q. And it says, "The CP then 22 And then it goes on to state that 23 discusses the specific products, oxycodone ER, 23 the applicants are seeking applications for opioids without abuse-deterrent properties should 24 oxymorphone ER, and buprenorphine implant and the 24

	Page 265		Page 266
1	not be approved and that the FDA should work with	1	petition would affect the generic Teva business
2	sponsors to gather and report the needed data to	2	negatively?
3	support new abuse-deterrent formulations.	3	A. Again, without reading the
4	Did I read that correctly?	4	petition, I'm not certain.
5	A. Yes.	5	Q. And then is it because at that
6	Q. What is your understanding of	6	time Teva did not manufacture any abuse-deterrent
7	abuse-deterrent formulations?	7	formulations of generic opioids?
8	A. Abuse-deterrent formulations,	8	MS. HILLYER: Objection to form,
9	meaning that it's more difficult to abuse than	9	calls for speculation.
10	normal, such as hard to crush, difficult to	10	THE WITNESS: Yeah, I'm not
11	snort, things like that.	11	certain.
12	Q. And then do you see that the	12	BY MR. GASTEEL:
13	summary then closes with, "It is difficult to	13	Q. Are you aware of any generic
14	assess the overall impact on Teva. It will	14	opioids that Teva was producing then or has ever
15	impact both the generic and brand opioid	15	produced, marketed and distributed that have
16	programs-negatively for the generics and	16	abuse-deterrent properties?
17	positively for the brand."	17	MS. HILLYER: Objection to form.
18	Did I read that correctly?	18	THE WITNESS: I don't believe so.
19	A. Actually, I didn't see where you	19	BY MR. GASTEEL:
20	are.	20	Q. Will you flip to I'm sorry.
21	Q. It's the two last sentences of	21	Go back to the first page of the
22	that paragraph, sir.	22	email.
23	A. Yes.	23	And then do you see that it
24	Q. Do you know why this citizen's	24	attaches the FDA opinion granting in part and
	Page 267		Page 268
1	denying in part this citizen's petition?		
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2		1 2	
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3	A. Where are you?Q. It's on the attachments line	2 3	MS. HILLYER: Objection to form. THE WITNESS: Sorry, can you
3 4	A. Where are you? Q. It's on the attachments line of	2 3 4	MS. HILLYER: Objection to form. THE WITNESS: Sorry, can you repeat your question?
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Where are you? Q. It's on the attachments line of A. Oh, okay. Q. Do you see that? A. Yes. Q. And then if you flip to the attachment, which I've included in your Exhibit 24, you'll see the FDA decision. Do you see that? A. Yes. Q. Will you flip to the second page, and it says "Background"? A. Yes. Q. And it begins with, "Abuse and misuse of prescription opioids is a public health epidemic." Did I read that correctly? A. Yes. Q. So it sounds like you disagree	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. HILLYER: Objection to form. THE WITNESS: Sorry, can you repeat your question? BY MR. GASTEEL: Q. Do you agree or disagree with the statement in this FDA ruling that "Abuse and misuse of prescription opioids is a public health epidemic"? A. I agree with that. Q. And that's going as far back as 2013. Right? A. That's when this is from, yes. Q. And it says, "According to the Centers for Disease Control and Prevention sales of prescription opioids in the United States quadrupled from 1999 to 2010." Did I read that correctly? A. Yes. Q. "Overdose deaths involving" those "products increased commensurately over the same
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Where are you? Q. It's on the attachments line of A. Oh, okay. Q. Do you see that? A. Yes. Q. And then if you flip to the attachment, which I've included in your Exhibit 24, you'll see the FDA decision. Do you see that? A. Yes. Q. Will you flip to the second page, and it says "Background"? A. Yes. Q. And it begins with, "Abuse and misuse of prescription opioids is a public health epidemic." Did I read that correctly? A. Yes. Q. So it sounds like you disagree with the FDA that abuse and misuse of prescription opioids is a public health epidemic.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. HILLYER: Objection to form. THE WITNESS: Sorry, can you repeat your question? BY MR. GASTEEL: Q. Do you agree or disagree with the statement in this FDA ruling that "Abuse and misuse of prescription opioids is a public health epidemic"? A. I agree with that. Q. And that's going as far back as 2013. Right? A. That's when this is from, yes. Q. And it says, "According to the Centers for Disease Control and Prevention sales of prescription opioids in the United States quadrupled from 1999 to 2010." Did I read that correctly? A. Yes. Q. "Overdose deaths involving" those "products increased commensurately over the same period, from 4,030 to 16,651." Did I read that correctly?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Where are you? Q. It's on the attachments line of A. Oh, okay. Q. Do you see that? A. Yes. Q. And then if you flip to the attachment, which I've included in your Exhibit 24, you'll see the FDA decision. Do you see that? A. Yes. Q. Will you flip to the second page, and it says "Background"? A. Yes. Q. And it begins with, "Abuse and misuse of prescription opioids is a public health epidemic." Did I read that correctly? A. Yes. Q. So it sounds like you disagree with the FDA that abuse and misuse of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. HILLYER: Objection to form. THE WITNESS: Sorry, can you repeat your question? BY MR. GASTEEL: Q. Do you agree or disagree with the statement in this FDA ruling that "Abuse and misuse of prescription opioids is a public health epidemic"? A. I agree with that. Q. And that's going as far back as 2013. Right? A. That's when this is from, yes. Q. And it says, "According to the Centers for Disease Control and Prevention sales of prescription opioids in the United States quadrupled from 1999 to 2010." Did I read that correctly? A. Yes. Q. "Overdose deaths involving" those "products increased commensurately over the same period, from 4,030 to 16,651."

	Page 269		Page 270
1	Q. "By 2010 prescription opioids	1	abuse-deterrent properties to be a public health
2	were involved in more than 75 percent of all	2	priority and supports that priority in several
3	prescription drug-related overdose deaths."	3	ways."
4	Did I read that correctly?	4	Did I read that correctly?
5	A. Yes.	5	A. Yes.
6	Q. Do those numbers trouble you,	6	O. Did Teva also think that
7	sir?	7	abuse-deterrent properties was important was a
8	MS. HILLYER: Objection to form.	8	public health priority in 2013?
9	THE WITNESS: I've never	9	MS. HILLYER: Objection to form.
10	considered those numbers before. I never	10	THE WITNESS: I'm not certain.
11	thought about it.	11	BY MR. GASTEEL:
12	BY MR. GASTEEL:	12	Q. But at that time it was not
13	Q. Well, as you're presented with	13	manufacturing any opioids that had
14	them today, do those numbers trouble you?	14	abuse-deterrent properties. Correct?
15	MS. HILLYER: Same objection.	15	MS. HILLYER: Objection to form.
16	THE WITNESS: Again, I don't have	16	THE WITNESS: I don't believe so.
17	an opinion on it.	17	
18	BY MR. GASTEEL:	18	(Deposition Exhibit No.
19	Q. Will you flip to the next page,	19	Teva-Tomsky-25, Email chain, top one
20	beginning with section A, "Abuse-Deterrent	20	dated 1/14/2014, Bates stamped
21	Opioids."	21	TEVA_MDL_A_10197053 and
22	A. Okay.	22	TEVA_MDL_A_10197054, was marked for
23	Q. And it says, "FDA considers the	23	identification.)
24	development of opioid analgesics with	24	
	Page 271		
	Page 2/1		Page 272
1	BY MR. GASTEEL:	1	
1 2		1 2	Fage 272 filed the citizen's petition. A. Yes.
	BY MR. GASTEEL:		filed the citizen's petition.
2	BY MR. GASTEEL: Q. You've just been handed a	2	filed the citizen's petition. A. Yes.
2 3	BY MR. GASTEEL: Q. You've just been handed a document that we have marked as Exhibit 25. And	2 3	filed the citizen's petition. A. Yes. Q. And then the email from Mr.
2 3 4	BY MR. GASTEEL: Q. You've just been handed a document that we have marked as Exhibit 25. And it's an email from January 2014 from Gary Buehler	2 3 4	filed the citizen's petition. A. Yes. Q. And then the email from Mr. Buehler to you and a variety of other people on
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. GASTEEL: Q. You've just been handed a document that we have marked as Exhibit 25. And it's an email from January 2014 from Gary Buehler to a variety of people, including you. Do you see that? A. Yes. Q. And it is also forwarding on an email from Gina Elton from January 13, 2014. Do you see that? A. Yes. Q. And then the email from Gina Elton on Monday, January 13, 2014 has another one of these tables that we saw in the previous document. Do you see that? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	filed the citizen's petition. A. Yes. Q. And then the email from Mr. Buehler to you and a variety of other people on January 14, 2014 summarizes the citizen's petition. Do you see that? A. Yes. Q. And do you see the last I'm sorry, the second to last paragraph, it says, "It is clear that this CP is a protest by a highly principled organization against the approval of Zohydro ER because it did not contain abuse-deterrent technology." Did I read that correctly? A. Sorry, I didn't follow where you are.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. GASTEEL: Q. You've just been handed a document that we have marked as Exhibit 25. And it's an email from January 2014 from Gary Buehler to a variety of people, including you. Do you see that? A. Yes. Q. And it is also forwarding on an email from Gina Elton from January 13, 2014. Do you see that? A. Yes. Q. And then the email from Gina Elton on Monday, January 13, 2014 has another one of these tables that we saw in the previous document. Do you see that? A. Yes. Q. And it has formulated or formatted it in the same way, and it again is tracking another citizen's petition that has been filed with the FDA. Right? A. Yes, it appears so. Q. And then this one is from the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	filed the citizen's petition. A. Yes. Q. And then the email from Mr. Buehler to you and a variety of other people on January 14, 2014 summarizes the citizen's petition. Do you see that? A. Yes. Q. And do you see the last I'm sorry, the second to last paragraph, it says, "It is clear that this CP is a protest by a highly principled organization against the approval of Zohydro ER because it did not contain abuse-deterrent technology." Did I read that correctly? A. Sorry, I didn't follow where you are. Q. Sure. It's the third paragraph there, beginning "It is clear." A. Yes. Q. And then Mr. Buehler am I
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. GASTEEL: Q. You've just been handed a document that we have marked as Exhibit 25. And it's an email from January 2014 from Gary Buehler to a variety of people, including you. Do you see that? A. Yes. Q. And it is also forwarding on an email from Gina Elton from January 13, 2014. Do you see that? A. Yes. Q. And then the email from Gina Elton on Monday, January 13, 2014 has another one of these tables that we saw in the previous document. Do you see that? A. Yes. Q. And it has formulated or formatted it in the same way, and it again is tracking another citizen's petition that has been filed with the FDA. Right? A. Yes, it appears so.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	filed the citizen's petition. A. Yes. Q. And then the email from Mr. Buehler to you and a variety of other people on January 14, 2014 summarizes the citizen's petition. Do you see that? A. Yes. Q. And do you see the last I'm sorry, the second to last paragraph, it says, "It is clear that this CP is a protest by a highly principled organization against the approval of Zohydro ER because it did not contain abuse-deterrent technology." Did I read that correctly? A. Sorry, I didn't follow where you are. Q. Sure. It's the third paragraph there, beginning "It is clear." A. Yes. Q. And then Mr. Buehler am I saying his name correctly?

	Page 273		Page 274
1	film?	1	Do you see that?
2	A. Yes.	2	A. Yes.
3	Q. He closes that paragraph with a	3	Q. Do you know why he thought that
4	claim that "Drug abuse in this country is an	4	this particular citizen's petition was not going
5	epidemic."	5	to impact Teva?
6	Did I read that correctly?	6	A. I'm not certain.
7	A. Yes.	7	Q. Do you know how often you receive
8	Q. "I do not believe that	8	these emails about citizen's petitions from the
9	abuse-deterrent products will solve the problem,	9	FDA?
10	but they would certainly be a start in addressing	10	A. So when Gary was here, we'd
11	the impact of this problem."	11	receive them quite regularly. But since Gary has
12	Did I read that correctly?	12	left, I would say they're few and far between.
13	A. Yes.	13	Although the legal team has started taking over
14	Q. Do you share that view, that	14	the responsibility for circulating these.
15	abuse-deterrent products will be a start in	15	Q. Okay. And best guess, about how
16	addressing the impact of the drug abuse in this	16	often do you receive these types of emails about
17	country that Mr. Buehler was describing in this	17	citizen's petitions at the FDA?
18	email?	18	MS. HILLYER: Objection to form.
19	MS. HILLYER: Objection to form.	19	THE WITNESS: Roughly a couple
20	THE WITNESS: I haven't thought	20	times a month maybe.
21	about it.	21	
22	BY MR. GASTEEL:	22	(Deposition Exhibit No.
23	Q. And then he closes that, "This CP	23	Teva-Tomsky-26, Email dated November 21,
24	should not impact Teva."	24	2017, Bates stamped TEVA_MDL_A_11731225
	Page 275		
	rage 273		Page 276
1	through TEVA_MDL_A_11731228, was marked	1	Page 276 is the liaison between FDA and the company, I
1 2		1 2	
	through TEVA_MDL_A_11731228, was marked		is the liaison between FDA and the company, I
2	through TEVA_MDL_A_11731228, was marked	2	is the liaison between FDA and the company, I send out similar emails for any guidances that
2	through TEVA_MDL_A_11731228, was marked for identification.)	2	is the liaison between FDA and the company, I send out similar emails for any guidances that are issued.
2 3 4	through TEVA_MDL_A_11731228, was marked for identification.) BY MR. GASTEEL:	2 3 4	is the liaison between FDA and the company, I send out similar emails for any guidances that are issued. Q. Sure. And then you also included
2 3 4 5	through TEVA_MDL_A_11731228, was marked for identification.) BY MR. GASTEEL: Q. Do you see that this, sir?	2 3 4 5	is the liaison between FDA and the company, I send out similar emails for any guidances that are issued. Q. Sure. And then you also included the statement from the FDA commissioner, Dr.
2 3 4 5 6	through TEVA_MDL_A_11731228, was marked for identification.) BY MR. GASTEEL: Q. Do you see that this, sir? This is an email that you sent on	2 3 4 5 6	is the liaison between FDA and the company, I send out similar emails for any guidances that are issued. Q. Sure. And then you also included the statement from the FDA commissioner, Dr. Gottlieb. Right? A. Yes. Q. Is Dr. Gottlieb still the FDA
2 3 4 5 6 7	through TEVA_MDL_A_11731228, was marked for identification.) BY MR. GASTEEL: Q. Do you see that this, sir? This is an email that you sent on November 21, 2017 to a variety of people I assume at Teva. Correct? A. Yes.	2 3 4 5 6 7	is the liaison between FDA and the company, I send out similar emails for any guidances that are issued. Q. Sure. And then you also included the statement from the FDA commissioner, Dr. Gottlieb. Right? A. Yes. Q. Is Dr. Gottlieb still the FDA commissioner today?
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Q. And that would be the types of opioids that Teva has been manufacturing for opioids that Teva has been manufacturing for several years. Correct? 18 and when patients use them as directed, and when licensed pharmacists dispense Q. You recall today that Mr. 20 them as directed, these medicines still serve a medical need to patients who need about I believe it's Exhibit 2, which is the document that listed Teva's opioid products and 23 BY MR. GASTEEL:		* *		
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22 about I believe it's Exhibit 2, which is the 22 them. 23 document that listed Teva's opioid products and 23 BY MR. GASTEEL:		•		
document that listed Teva's opioid products and 23 BY MR. GASTEEL:				_
2.1 Its share of market share of prescription 2.7 Q. Suite. But feva is aware that	. 40	accument mat nated Teva's opioid products and	43	DI MIK. OADIDEE.
ı		its share of market share of prescription	24	O Sure Rut Teva is aware that

	Page 281		Page 282
1	there is large-scale abuse and misuse, in other	1	market, sell and distribute those throughout the
2	words, there's large scale use that is outside of	2	country, including in states like the state of
3	the process of people taking them as directed	3	Tennessee. Right?
4	when a licensed pharmacist dispenses them	4	A. I'm not certain, actually.
5	pursuant to a valid prescription. Right?	5	Q. You're not certain as to whether
6	MS. HILLYER: Objection to form.	6	or not Teva continues to market, sell, distribute
7	THE WITNESS: Yes. And FDA is	7	and produce prescription opioids throughout the
8	aware of that information as well, and	8	country?
9	that's why there's risk mitigation	9	A. I don't know which products Teva
10	strategies put in place as well.	10	is actively marketing right now, especially
11	BY MR. GASTEEL:	11	specific to opioids, and as well as whether or
12	Q. And those risk mitigation	12	not they're sold in Tennessee or dispensed in
13	strategies have been in place for several years.	13	Tennessee.
14	Right?	14	Q. Were you ever on an FDA advisory
15	A. Yes.	15	committee regarding Opana ER?
16	Q. And we've seen, at least as of	16	A. No.
17	2017, the commissioner of the FDA, in statements	17	Q. Do you recall whether or not
18	that you've forwarded to your colleagues at Teva,	18	do you recall let me back up.
19	is continuing to talk about the staggering human	19	Do you know what Opana ER is?
20	and economic toll created by opioid abuse and	20	A. Yes.
21	addiction. Right?	21	Q. What is it?
22	A. Correct. But FDA still hasn't	22	A. Oxymorphone extended release.
23	pulled those products off the market yet.	23	
24	Q. And then Teva continues to	24	Q. And that was a branded product that was manufactured by Endo Pharmaceuticals.
24	Q. And then Teva continues to	24	that was manufactured by Endo Fharmaceuticais.
	Page 283		Page 284
1	Right?	1	BY MR. GASTEEL:
2	A. I believe so.	2	Q. Yes.
3	Q. And then there was a generic	3	A. Nothing stands out in my mind
4	version of that product that Teva also produced.	4	about it.
5	Right?	5	MR. GASTEEL: Mr. Tomsky, I
6	MS. HILLYER: Objection to form.	6	believe that's all the questions I have
7	THE WITNESS: I believe so.	7	for you.
8	Again, I'm not certain whether or not we	8	MS. HILLYER: I just have one
9	manufactured it.	9	follow-up.
10	BY MR. GASTEEL:	10	
11	Q. Do you recall anything	11	EXAMINATION
12	specifically about the reformulation of Opana ER	12	
13	that included an abuse-deterrent property?	13	BY MS. HILLYER:
14	A. Vaguely.	14	Q. Mr. Tomsky, when you referenced
15	Q. You don't recall anything	15	that you received emails from Mr. Buehler
16	specifically about that?	16	concerning citizen's petitions, and you mentioned
17	A. No.	17	that you would receive them perhaps a couple of
18	Q. Do you recall that, at some	18	times a month, were those concerning all
19	point, Teva pulled an ANDA related to oxymorphone	19	products, all generics?
20	ER tablets that was pending in front of the FDA	20	A. Yes. Anything that Teva had
21	in and around 2017?	21	pending or approved.
22	MS. HILLYER: Objection to form.	22	MS. HILLYER: Okay. I have no
23	THE WITNESS: Pulled meaning	23	further questions.
24	withdrew?	24	THE VIDEOGRAPHER: Okay. That
			1220 old 11220 oldy. That

	Page 285	Page 286
1	concludes today's deposition. The time	1
2	is 3:30 p.m.	2 CERTIFICATE
3	(Witness excused.)	3
4	(Deposition concluded at	4 5 I HEREBY CERTIFY that the witness
5	approximately 3:30 p m.)	was duly sworn by me and that the deposition is a
6	approximatery 3.30 p iii.)	6 true record of the testimony given by the
7		witness.
		7
8		It was requested before 8 completion of the deposition that the witness,
9		SCOTT D. TOMSKY, have the opportunity to read and
10		9 sign the deposition transcript.
11		10
12		12
13		13
14		
15		14 ANN MARIE MITCHELL, a Federally Approved Certified Realtime
16		15 Reporter, Registered Diplomate
17		Reporter, Registered Merit Reporter and
18		16 Notary Public
19		17 18
20		19 (The foregoing certification of
21		20 this transcript does not apply to any
22		21 reproduction of the same by any means, unless
23		22 under the direct control and/or supervision of the certifying reporter.)
24		24
	Page 287	Page 288
1	Page 287 INSTRUCTIONS TO WITNESS	Page 288
1 2		
		1
2	INSTRUCTIONS TO WITNESS	1 ERRATA
2	INSTRUCTIONS TO WITNESS Please read your deposition over	1 ERRATA 2
2 3 4	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections.	1
2 3 4 5	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate	1
2 3 4 5 6	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections	1
2 3 4 5 6 7	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.	ERRATA 2 3 4 PAGE LINE CHANGE 5 6 REASON: 7 8 REASON:
2 3 4 5 6 7 8	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the	ERRATA 2 3 4 PAGE LINE CHANGE 5 6 REASON: 7 8 REASON: 9
2 3 4 5 6 7 8	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it.	ERRATA 2 3 4 PAGE LINE CHANGE 5 6 REASON: 7 8 REASON: 9 10 REASON:
2 3 4 5 6 7 8 9	INSTRUCTIONS TO WITNESS Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to	ERRATA 2 3 4 PAGE LINE CHANGE 5 6 REASON: 7 8 REASON: 9 10 REASON: 11
2 3 4 5 6 7 8 9 10	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet,	ERRATA 2 3 4 PAGE LINE CHANGE 5 6 REASON: 7 8 REASON: 9 10 REASON: 11 12 REASON:
2 3 4 5 6 7 8 9 10 11	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.	ERRATA 2
2 3 4 5 6 7 8 9 10 11 12 13	Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made. After doing so, please sign the errata sheet and date it. You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition. It is imperative that you return	ERRATA ERRATA PAGE LINE CHANGE REASON:
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Case: 1:17-md-02804-DAP Doc #: 1985-3 Filed: 07/24/19 73 of 73. PageID #: 255368

	Page	289
1		
2	ACKNOWLEDGMENT OF DEPONENT	
3		
4	I,, do	
5	hereby certify that I have read the foregoing	
6	pages, 1 - 289, and that the same is a correct	
7	transcription of the answers given by me to the	
8	questions therein propounded, except for the	
9	corrections or changes in form or substance, if	
10	any, noted in the attached Errata Sheet.	
11		
12		
13		
14	SCOTT D. TOMSKY DATE	
15		
16		
17	Subscribed and sworn	
	to before me this	
18	day of, 20	
19	My commission expires:	
20		
21	Notary Public	
22		
23		
24		